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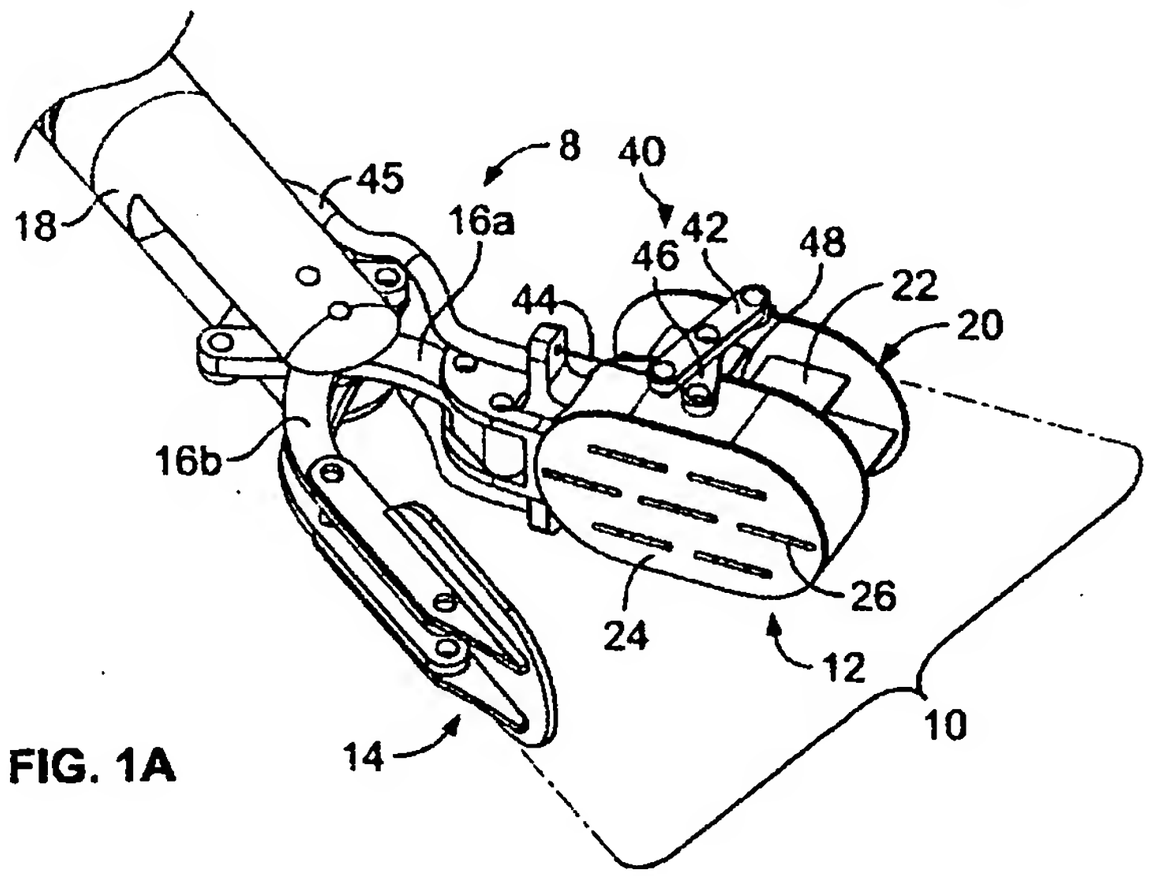

FIG. 1A

(57) Abstract: A device for acquiring and stapling multiple tissues regions within a subject's stomach, by introducing the device transorally into the stomach, is disclosed. The device includes a multi-fire staple head designed for reciprocal motion along an axis between a compact condition in which the head can be inserted into the stomach transvrally and an expanded tissue-acquisition condition, a shaft to which the head is attached and by which the head in its compact condition can he introduced transorally into the stomach, and a tissue-acquisition device for acquiring tissue within the stomach. Also disclosed is a method for acquiring and stapling multiple tissues regions within a patient's stomach, a multi-fire stapler device that indexes different rows of staples, and a multi-first stapler device that with multiple staple cartridges.

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MULTI-FIRE STAPLING SYSTEMS AND METHODS FOR DELIVERING ARRAYS OF STAPLES

TECHNICAL FIELD OF THE INVENTION

[0001] The present invention relates generally to the field of tissue acquisition and stapling.

BACKGROUND

[0002] Surgical staplers have been in clinical use for many years. They have become a standard tool used by surgeons in procedures requiring tissue apposition, ligation, resection and/or anastomosis. Staplers reduce overall procedure time by eliminating the need for the time-consuming placement of sutures. Staplers can reduce blood loss in certain procedures involving resection of tissue to be stapled, by allowing tissue cutting/resection to be performed after the tissue is compressed and stapled. For example, a pair of staple rows is first formed, and then the tissue is cut along a line between the staple rows.

[0003] Surgical staplers are configured to fire the multiple staples of a staple array (e.g. a linear array such as a staple line, a circular array etc.) in a single shot. Early staplers comprised reusable handles and disposable staple cartridge loads holding a single staple array. Subsequent staplers used disposable handles and disposable cartridge loads. During clinical use of the prior art staplers, spent cartridges must be removed from the handles and replaced with fresh cartridges. Thus, a stapler carrying a single charge of staples is fired into the tissue and then removed from the patient. The spent cartridge is ejected and a new cartridge is loaded for the next staple line. The stapler is reintroduced into the body and the process is repeated for the next line or array of staples to be applied to tissue. The need for constant reloading of the stapler is particularly time consuming in transoral natural orifice surgeries, as the time required for repositioning the stapler head after removing the device from the stomach or other body cavity is not insignificant. Moreover, the requirement for multiple staple cartridges per procedure adds to the overall cost of the procedure.

SUMMARY OF THE INVENTION

[0004] In one aspect, the invention includes a device for acquiring and stapling multiple tissue regions within a subject's stomach, by introducing the device transorally into the subject's stomach. The device includes, in operative condition, (a) a multi-fire staple head designed for reciprocal motion along an axis between a compact condition in which the head can be inserted into the stomach transorally and an expanded tissue-acquisition

condition, (b) a shaft to which the head is attached and by which the head in its compact condition can be introduced transorally into the stomach, and (c) a tissue-acquisition device for acquiring tissue within the stomach,

[0005] The multi-fire staple head comprises (i) a staple-holding member having a plurality of staple-holding chambers arrayed in a pattern about the axis, each chamber terminating at a staple-ready position, a plurality of staples held within each chamber, with one of the staples in each chamber being positioned at the staple-ready position in that chamber, and a staple driver for engaging those staples in the staple-ready position within each chamber and driving the engaged staples across the tissue-contact surface and out of the staple-holding member, when the staple driver is moved from a firs to a second position, wherein movement of the staple driver from its second to its first position results in the advance of a new staple in each chamber to a staple-ready position.

[0006] Also included in the stapler head are (ii) an anvil member, (iii) a tissue-capture chamber defined between confronting surfaces of the staple-holding and anvil members, and (iv) structure coupling the staple-holding and anvil members for reciprocal motion along the axis toward and away from one another between the compact condition and the expanded condition at which the tissue-acquisition chamber has an expanded areal dimension and a tissue fold within the chamber is captured between the staple-holding anvil members.

[0007] The plurality of staple-holding chambers may be arranged symmetrically about the axis. In one exemplary embodiment, the plurality of staple-holding chambers include four chambers arranged in a square pattern about the axis.

[0008] The stapler head may further include a cutting element which moves along the axis, independently of or coupled to the staple driver, to form a hole in a tissue fold being stapled.

[0009] The tissue-acquisition device may be a vacuum chamber contained within the staple-holding member, and the device may further include a vacuum port for applying a vacuum to the chamber, thus to draw tissue into the chamber. Alternatively, the tissue-acquisition device may include a mechanical grasper for engaging a tissue fold and drawing the engaged fold into the tissue-capture chamber.

[0010] In a more general aspect of the device for acquiring and stapling multiple tissue regions within a subject's stomach, the multi-fire staple head may be designed for either reciprocal motion between compact and expanded conditions or for pivotal motion between open and closed conditions, where the plurality of staple-holding chambers in the

stapling head of the latter embodiment are arranged for forming a non-linear array of staples in the captured tissue.

[0011] In another aspect, the invention includes a method for acquiring and stapling multiple tissue regions within a subject's stomach. The method includes the steps of:

(a) transorally introducing into the patient's stomach a multi-fire-stapling device and a tissue-acquisition device,

(b) manipulating the tissue-acquisition device to engage stomach tissue at a selected stomach region;

(c) drawing the engaged tissue into a tissue-acquisition chamber in the stapling device, thus forming a tissue fold within the chamber,

(d) activating the stapling device to place a plurality of staples in the fold within the chamber,

(e) releasing the stapled tissue fold formed in step (d), and

(f) without having to withdraw the stapling or acquisition devices from the stomach, repeating step (a)-(e) until a desired number of stapled tissue folds are formed within the subject's stomach.

[0012] The multi-fire stapling device introduced into the stomach may be designed for reciprocal motion along an axis between a compact condition in which the head can be inserted into the stomach transorally and an expanded tissue-acquisition condition. One exemplary reciprocal motion multi-fire staple head is described above. This embodiment may be designed to form a square array of four staples in the captured tissue fold. The stapler head may includes a cutting element that moves along the axis independently of or couple to the staple driver, and stapling step (d) includes forming a hole in the tissue fold being stapled.

[0013] The tissue-acquisition device may be a vacuum chamber in the stapler head, step (b) may include manipulating the stapling head to place the vacuum chamber against a tissue region to be acquired, and applying a vacuum to the chamber to engage the tissue region, and step (c) includes continuing to apply the vacuum while moving the stapling head to its expanded condition, to draw engaged tissue into the vacuum chamber.

[0014] The tissue-acquisition device in the stapler head may include a mechanical grasper for engaging a tissue fold, step (b) includes manipulating the grasper to engage a tissue region to be acquired, and step (c) moving the grasper and engaged tissue region into the tissue-acquisition chamber of the stapling device.

[0015] Also disclosed is a device for stapling multiple tissue regions. The device includes in operative condition, (a) a staple-holding member having a plurality of rows of plural staple-holding chambers, and at least one staple held within each chamber, with at least one staple in each chamber being positioned at a staple-ready position in that chamber, (b) an anvil member that is movable with respect to the staple holding member, for stapling tissue supported between the staple-holding member and anvil, and (c) a staple driver carried on said staple holding member for movement from a first to a second position at which those staples in the staple-ready position within a selected row of staple-holding chambers are advanced from the staple-holding member against the anvil member, to form a linear array of staples through tissue supported between the two members.

[0016] The device may include a separate staple driver for each linear array of chambers.

[0017] The staple driver may include a staple-engaging wedge that travels along a row of staple in a linear array, successively engaging those staples in a staple-ready position within a single linear array of chambers.

[0018] The rows of staple chambers may be disposed on a rotating barrel, for successive rotation to row positions at which a selected row is positioned adjacent said anvil, such that activation of a fixed-position staple driver is effective to eject staples from the chambers in that row against the anvil, thereby stapling tissue captured between the chamber row and anvil.

[0019] In still another aspect, the invention includes a device for performing multiple stapling operations within a hollow organ of a subject. The device includes (a) a staple-holding member having a cartridge housing and a staple driver that is movable within the member between first and second positions, (b) an anvil member mounted on the staple-holding member for pivoting thereon, for movement toward and away a stapling position, and (c) a plurality of staple cartridges. Each cartridge has (i) a plurality of staples, (ii) at least one driver slot through which the staple driver can be moved from its first to its second positions to eject one or more staples from the cartridge, when the two members are moved to their stapling position, and (iii) locking structure that locks a cartridge within the cartridge housing, when that cartridge is introduced into the staple-holding member. Also included in the device is (d) a release mechanism associated with the staple-holding member for releasing a cartridge from the staple-holding member after the cartridge staples have been ejected, and (e) means for supporting the cartridges for successive loading into and release from the staple-holding member.

[0020] The release mechanism may include a spring-loaded staple driver lever that acts to push a cartridge from the staple-holding member after the staple driver has been moved, against a spring bias, to its second position, to eject staples from the cartridge.

[0021] The staple driver may include a staple-engaging wedge that travels along a row of staples in a linear array, successively engaging cartridge staples.

[0022] The cartridges may be supported for successive loading into the cartridge chamber of the staple-holding member as a string of cartridges, and supporting means (e) includes a flexible tether or pivoting joint connections joining the exit end of one cartridge to the entry end of another.

[0023] The disclosed multi-fire staple housings and cartridges are particularly beneficial for performing multiple tissue acquisition and stapling steps within the stomach, such as during stomach partitioning procedures in which the stomach is partitioned from the inside by connecting tissue within the stomach (see commonly owned Application No. 12/119,329, filed May 12,2008, entitled DEVICES AND METHODS FOR STOMACH PARTITIONING), or for forming tissue plications within the stomach for use in retaining stomach implants (see commonly owned Application No. 12/175,242, filed July 17, 2008, entitled ENDOSCOPIC IMPLANT SYSTEM AND METHOD and Application No. 12/050,169, filed March 18,2008, entitled ENDOSCOPIC STAPLING DEVICES AND METHODS).

[0024] These and other objects and features of the present invention will become more fully apparent when the following detailed description of the invention is read in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] Fig. 1A is a perspective view of a first embodiment of a multi-fire stapler head, showing the jaws in the open position and the staple driver in the pre-firing position.

[0026] Fig. 1B is similar to Fig. 1A and shows the jaws in the closed position and the staple driver in the pre-firing position.

[0027] Fig. 1C is similar to Fig. 1A and shows the jaws in the closed position and the staple driver in the firing position.

[0028] Fig. 2 is a plan view of the stapler housing, with the face plate removed.

[0029] Fig. 3A is a perspective view showing a longitudinal cross-section of the staple housing with the back plate removed.

[0030] Fig. 3B is a perspective view showing a lateral cross-section of the staple housing with the back plate removed.

[0031] Fig. 4 is a perspective view of the staple advancing plate and one of the two springs provided on the plate.

[0032] Fig. 5A is similar to Fig. 2 but shows an alternate type of spring in the feed mechanism.

[0033] Fig. 5B shows a single cell of the embodiment of Fig. 5A, with the spring replaced by an elastomeric member.

[0034] Fig. 6 shows a cross-section view of a portion of the staple housing and a portion of the staple driver in the region of a single one of the cells.

[0035] Figs. 7 A - 7C are a sequence of side elevation views schematically illustrating movement of an alternative staple driver to drive staples from a staple housing into tissue.

[0036] Figs. 8A - 8E are a sequence of side elevation views schematically illustrating movement of a second alternative staple driver to drive staples from a staple housing into tissue.

[0037] Fig. 9A shows a plan view of an alternate staple housing with the back plate removed.

[0038] Figs. 9B - 9E are a sequence of side elevation views schematically illustrating movement of a staple driver to drive staples from the staple housing of Fig. 9A into tissue.

[0039] Figs. 10A through 10C are a sequence of perspective views schematically showing driving of a staple from a ready position towards tissue to be stapled, and subsequent reloading of the next staple from the stack into the ready position.

[0040] Figs. 11 and 12 are perspective views illustrating one method of forming a staple stack for use in the stapler of Fig. 1A.

[0041] Figs. 13 through 15 are a sequence of steps illustrating use of the stapler of Fig. 1A, in which Fig. 13 is a side elevation view showing the jaws closed and the staple driver in the retracted position, Fig. 14 is a side elevation view showing the jaws opened and the staple driver in the retracted position, and Fig. 15 is a side elevation view showing the jaws closed and the stapler driver extending through the staple housing to drive an array of staples.

[0042] Fig. 16 is a plan view of a second embodiment of a stapler employing an alternate multi-fire staple housing.

[0043] Fig. 17 is an exploded view of the staple cartridge of the Fig. 16 stapler.

[0044] Fig. 18 is another exploded view of the staple cartridge of Fig. 17, in which the staples, staple advancing elements, and staple pusher are not shown for clarity.

[0045] Fig. 19 is a perspective view of the staple cartridge of Fig. 17 in a partially assembled state, with staples and staple advancing elements loaded, but with the front housing separated to permit viewing of the staples and staple advancing elements. The compression band and staple pusher are not shown.

[0046] Fig. 20 is a perspective view of the staple pusher for the staple cartridge of Fig. 17.

[0047] Fig. 21A is a perspective view of the staple cartridge of Fig. 17, with the staple pusher in the retracted position.

[0048] Fig. 21B is similar to Fig. 21A and shows the staple pusher in the staple driving position to drive staples from the staple cartridge.

[0049] Fig. 22 is a top plan view of the staple cartridge of Fig. 17, showing in hidden lines the staple stacks and staple advancing elements.

[0050] Figs. 23A through 23C are a sequence of cross-section views of the cartridge showing driving of staples from a ready position towards tissue to be stapled, and subsequent reloading of the next staples from the staple stacks into the ready position.

[0051] Fig. 24 is a perspective view of an alternative embodiment of a staple head, in which a spent cartridge is positioned in the background, a second cartridge is within the staple housing, and a third cartridge is awaiting advancement into the staple housing to replace the second cartridge.

[0052] Fig. 25 is a perspective view illustrating a first cartridge advancing into the staple housing and a second cartridge coupled to the first cartridge.

[0053] Figs. 26A through 26E are a sequence of drawings illustrating the steps of driving staples from a cartridge, and the advancement of a second cartridge into the staple housing.

[0054] Fig. 27 illustrates a barrel-type multi-fire stapler constructed in accordance with an embodiment of the invention.

DETAILED DESCRIPTION

[0055] Fig. 1A generally shows a stapler or stapler device 8 employing a multi-fire stapler head 10. Stapler head 10 includes a staple housing or staple-holding member 12 and a corresponding anvil or anvil member 14 carried by opposed jaw members 16a, 16b on the distal portion of an elongate shaft 18. That is, the anvil is mounted on the staple-holding

member for pivoting movement toward and away from open (Fig. 1A) and closed (Figs. 1B and 1C) positions. The staple-holding member 12 has an array of staples each in a staple delivery location or "ready position" ready to be fired into target tissue. A staple driver 20 in the staple-holding member is positioned for advancement from a first position shown in Fig. 1B to a second position shown in Fig. 1 C so as to drive the ready-position staples from the staple head 12 into the tissue using staple pushers 22. During use, the staples in the ready positions are fired into the target tissue using the staple pushers 22. After the array has been fired, and the staple driver is moved from its second position back to its first position, feed mechanisms within the staple housing advance a second array of staples from one or more staple storage locations into the ready positions in preparation for firing of the second array.

[0056] Referring again to Fig. 1 A, stapler head 12 includes a face plate 24 having a number of openings 26 through which the staples exit the staple head 12 during stapling. The openings 26 are thus arranged in the pattern of the desired staple array, preferably a non-linear pattern such as the 2-3-2 pattern of offset staples seen in Fig. 2 . An internal feed mechanism within the staple housing 12 functions to feed staples from stacks of staples into ready positions, which are aligned with the openings 26. In the illustrated embodiments, separate feed mechanisms are used to move each staple of the array into its corresponding ready position. Other embodiments, however, may use feed mechanisms capable of feeding staples into multiple ready positions. Fig. 2 shows a plan view of the staple housing 12 in which the face plate 24 has been removed to reveal the feed mechanisms used to feed staples into ready positions. As shown, the staple housing 12 includes a plurality of cells or staple-holding chambers 28, the number of which corresponds to the number of staples in the array. Any number of shapes may be used for the cells 28, although in the illustrated embodiment, each cell 28 includes an intermediate section 29a and narrower end sections 29b. As will be appreciated below, the stapler head and anvil have corresponding faces, e.g., face plate 24, that move toward one another during a stapling operation, to capture a tissue fold between the two faces, holding the tissue fold during the stapling operation.

[0057] Each cell 28 contains a collection or stack 30 of staples disposed in the intermediate section 29a. One of the staples 30a is in a ready position 31 aligned with the corresponding opening 26 (Fig. 1A) of the overlying faceplate 24. In one of the end sections 29b is a feed mechanism which includes at least one spring 32 and a plate 34. As shown, one end of the spring 32 contacts a wall in the cell 28, and the other end contacts one face of the plate 34. The opposite face of the plate 34 is in contact with staple stack 30. The spring force against the plate 34 biases the end-most staple 30a in the ready position 31, in contact with

the walls 36. When a staple is advanced from the ready position into tissue, this spring force advances the stack's next staple into the ready position 31.

[0058] Various types of springs may be used in the feed mechanism. In the embodiment illustrated in Figs. 2 - 3B, a pair of compression springs 32 is used within each cell 28. As shown in Fig. 4, each spring 32 may be supported on one end by a protrusion or button 38 on the plate 34.

[0059] In alternate spring arrangements, the compression springs are replaced by one or more leaf springs 32a as shown in Fig. 5A and/or by one or more elastomeric spring elements 32b as shown in Fig. 5B. It should also be noted that Fig. 5A illustrates the staple stacks and feed mechanisms in a staple housing having a channel 35 through which a cutting blade can pass for tissue resection subsequent to stapling.

[0060] Fig. 6 is a cross-section view of a single cell and surrounding region of the staple housing 12. This figure illustrates that a back plate 48 is positioned on the opposite side of the staple housing 12 from the face plate 24, and includes openings 50 (only one of which is shown) aligned with the corresponding openings 26 (one shown) on the face plate 24. The openings 50 are positioned to permit a staple pusher to pass through them into the staple housing 12 to drive staples out the openings 26 in the face plate 24.

[0061] Features used to push staples from the ready position through the tissue will next be described. Referring to Fig. 1A, staple driver 20 includes a plurality of staple pushers 22 extending from a plate. A linkage 40 couples the staple driver 20 to the stapler head 12, with the staple pushers 22 aligned with openings 50 in the back plate 48 (Fig. 6).

[0062] Linkage 40 has a first link 42 having a first end pivotally coupled to the plate of the staple pusher 22 and a second end connected to a pull cable 44. Pull cable 44 extends through a cable housing 45 to a handle on the shaft. A second link 46 is pivotably coupled at one end to an intermediate section of the first link 42, and it is pivotably coupled at its other end to the staple housing 12. The linkage is configured such that application of tension to the pull cable 44 pivots the links 42, 46 from a first position shown in Figs. 1B to second position shown in Fig. 1C, thus driving the staple driver 20 towards the staple housing, causing staple pushers 22 to ass into the staple housing 12 and to drive the staples in the manner illustrated in Fig. 6.

[0063] Various other methods may be used to advance a staple pusher to drive a staple from the staple housing. Some alternate methods, each of which uses a translating staple driver, are shown schematically in Figs. 7 A through 9E.

[0064] Figs. 7 A - 7C illustrate a linear arrangement of staples 30a being driven from a staple housing 12 (which could be a cartridge or magazine) with a driver 52 moveable in a direction parallel to the back span of the staples. This motion could be generated with hydraulic pistons 51 as shown, or with pull cables, linkages, rotary input, as well as other means. Pushers 53 are positioned in contact with the back spans of the staples. The driver 52 includes a plurality of wedge elements 54 positioned such that as the driver is advanced, the sloped edges of the wedge elements 54 contact the pushers 53, causing the pushers to drive the staples 30a from their corresponding chambers in the staple housing (Figs. 7B and 7C. In a modification of this embodiment, the pusher 53 is provided with a single wedge element used to sequentially drive staples similar to the manner shown in Figs. 8A - 9E below.

[0065] In the example pictured in Figs. 7 A -7C, two staples 30a are driven at the same time, but any number of staples could be driven similarly. Multiple drivers 52 and corresponding rows of staples can exist in the same tool. Once the driver 52 has fully driven the staples from the housing, it is returned to the home position. The return could be active. with operator input, as in the case of a separate hydraulic circuit, or cable to return the mechanism, or passive, with the driver returning on its own with forces supplied by a spring or springs which were compressed during actuation. In the illustrated embodiment, springs 54 compressed by the pushers 53 during staple firing return the pushers 53 to their original position in the housing after the driver has moved out of their path. A feed mechanism within the housing 12 advances another round of staples into the ready position for the next actuation as disclosed elsewhere in this application.

[0066] Another embodiment illustrated in Figs. 8A - 8E is similar to the Fig. 7A-7C embodiment, but it employs a bi-directional staple deployment scheme. As shown, driver 52a includes a wedge element 54a having two sloped edges. During movement of the driver 52a in a first direction, a first set of staples 30a is sequentially driven into the tissue (Figs. SB and SC). Once the first set of staples has been fired, another staple set can be brought into the ready positions (in the return path of the driver), such that the return motion of the wedge element 54a can deploy the second set into the tissue. In a modification to the Fig. SA embodiment, a plurality of bi-directional wedge elements are positioned similar to the positions of the wedge elements in the Fig. 7A embodiment, allowing for simultaneous advancement using the multiple wedge elements on the driver. In this variation, movement of the driver in a first direction will drive a first set of staples and then movement of the driver in the opposite direction will drive the second set of staples fed into the ready positions vacated by the first staples.

[0067] In modifications to the embodiments of Figs. 7A and SA, the staples may be oriented in the staple housing such that the staple back spans are rotated 90 degrees from the position shown in Figs. 7A and SA (i.e. the staples are turned such that the back span extends into and out of the page in Figs. 7A and SA). One configuration using this design is shown in Figs. 9A - 9E. Fig. 9A shows the housing 12a with the back plate removed and shows only one row of drivers and staples for simplicity. In practice, each row would be filled with staples and each row could be driven into the anvil separately, or in groups, depending on the desired actuation scheme. Additionally, the staples could be arranged with the back spans at angles other than 90 degrees to the driver.

[0068] Referring to Figs. 9B - 9E, driver 52b includes a wedge 54b. The staple back spans are transverse to the direction of motion of the driver 52b. In Fig. 9B, the wedge is at its start position. To drive the staples, driver is pulled to the right by a cable, or other flexible element actuated by any means providing appropriate force. As the driver 52b travels, it forces the sloped caps 53b positioned above each the staple in a downward direction. The caps 53b drive the staples through the tissue and towards the anvil (not shown). As with the previous embodiments, a spring or other element may be used to return the caps to the original position. That is, the wedge or staple driver is carried on said staple holding member for movement from a first (Fig. 9A) to a second (Fig. 9E) position at which those staples in the staple-ready position within a selected linear array of chambers are advanced from the staple-holding member against the anvil member, to form a linear array of staples through tissue captured between the two members. The device may have a separate staple driver for each linear array of chambers, or a single staple driver could be positioned at a desired row of chambers. The chamber may contain a single staple or multiple staples that are fed to a staple-ready position with each firing, as described above.

[0069] In another embodiment, not shown the staple driver includes a plurality of wedges, one for each chamber, such that movement of the staple driver from its first to second position moves each wedge across the corresponding chamber, to eject a staple from that chamber.

[0070] The device illustrated in Fig. 9 includes (a) a staple-holding member having a plurality of rows of plural staple-holding chambers, and at least one staple held within each chamber, with at least one staple in each chamber being positioned at a staple-ready position in that chamber, (b) an anvil member that is movable with respect to the staple holding member, for stapling tissue supported between the staple-holding member and anvil, and (c) a staple driver carried on said staple holding member for movement from a first to a second

position at which those staples in the staple-ready position within a selected row of staple-holding chambers are advanced from the staple-holding member against the anvil member, to form a linear array of staples through tissue supported between the two members. In this embodiment, a separate staple driver is provided for each row of staples.

[0071] In a related embodiment, illustrated in Figs. 27, a multi-fire stapler, shown at 250, has a barrel 252 that rotates about a tube 255, to successively position each of a row of staple pairs, such as shown at 254, 256, into position for staple ejection against an anvil 258. When a staple row on the cartridge is rotated into a stapling position (row 257 in the figure) and a tissue is placed against this row, the anvil is brought against the staple-ejection region to capture the tissue therebetween, and a staple driver, e.g., staple-driving wedge that is pulled through tube 255, is activated to eject staples from that row against the anvil, forming two closely spaced rows of staples staples through the captured tissue fold.

[0072] Figs. 10A through 10C schematically illustrate operation of the staple pusher and automatic feed mechanism to fire a staple from the ready position and to then replace the fired staple in the ready position with the next staple in the stack. Referring to Fig. 10A, prior to staple firing, staple 30a is biased in the ready position due to the action of the spring force F imparted against the plate 34 by the spring (not shown in Fig. 10A). Staple pusher 22 is advanced as discussed above to fire the staple. Fig. 10B. Due to the constant spring force F against the plate 34, as soon as the staple 30a leaves the ready position, it is replaced in the ready position by the next staple 30b in the stack 30. Fig. 10C. This automatic reloading of staples into the ready position repeats itself as each staple 30a-30n in the cell is fired. After all staples 30a-30n have been fired, the staple housing may be reloaded with a new charge of staples if additional stapling is needed.

[0073] The stapler housings and staple cartridges disclosed herein may be used with any suitable staples or staple stacks. Staple stacks may be formed using a sheet of flat material 58 as shown in Fig. 11. Longitudinal score lines 60 are formed on one side of the sheet 58, and the ends 62 of the sheet are chamfered to create what will be the tips of the staple legs. The sheet 58 is bent into the shape shown in Fig. 12, with the score lines 60 serving as the dividing lines between what will become individual staples. With this arrangement, each time the staple pusher is driven, it causes the endmost staple to be sheared from the sheet of flat material and driven into the tissue.

[0074] Use of the stapler 10 will next be described. Prior to use, staple stacks 30 are loaded into the cells of the staple housing 12. With the jaws 16a, 16b in the closed position as in Fig. 13, the staple head 10 is advanced to the location of the tissue to be stapled. Next, a

20 control element on the handle of the stapler shaft is manipulated to open the jaws to the position shown in Fig. 14. Various configurations known to those skilled in the art may be used to open and close the jaws. The illustrated embodiment employs a linkage 64 coupled to the jaws 16a, 16b. Linkage 64 is actuated using a piston 66, which is moved distally using hydraulic or mechanical means to expand the linkage for opening the jaws (Fig. 14) and which is moved proximally to collapse the linkage and close the jaws (Fig. 13).

[0075] With the jaws 16a, 16b opened, the tissue to be stapled is positioned between the staple housing 12 and anvil 14. The stapler may be equipped with integrated tissue acquisition devices useful for this purpose. Suitable tissue acquisition devices are described in the following commonly owned applications: Application No. 12/119,329, filed May 12, 2008, entitled DEVICES AND METHODS FOR STOMACH PARTITIONING, and Application No. 12/050,169, filed March 18,2008, entitled ENDOSCOPIC STAPLING DEVICES AND METHODS, and Application No. 12/268,216, entitled TISSUE ACQUISITION DEVICES AND METHODS, filed on same date herewith (Attorney Docket BARO-2200). In that application, tissue is acquired into a vacuum head using a vacuum source, and then the acquired tissue is retained (e.g. for tissue positioning, manipulation) by a grasper. Alternatively, one or more independently movable mechanical instruments, e.g., a tissue grasper, may be used to acquire or engage tissue at a selected tissue region and move the grasped tissue between the jaws of the stapler, i.e., between the cartridge (staple-holding member) and anvil.

[0076] Once tissue is captured between the cartridge and anvil, the jaws are again closed (Fig. 13) to close the staple housing and anvil against the tissue, thereby compressing the tissue in preparation for stapling. The cable 44 (Fig. 1A) is actuated to drive the staple driver 20 towards the staple housing 12, thus driving the staple pushers 22 into the staple housing 12 (Fig. 15) to fire the array of staples through the tissue. As is typical with staplers, the free legs of the staples fold against corresponding recesses (not shown) on the anvil surface.

[0077] When tension is released from the cable 144, springs (not shown) force the staple driver 20 back into the retracted position shown in Fig. 13. Once the staple driver 20 withdraws from the staple housing, that is, moved from its second to its first position, a new staple moves into the ready position in each cell (as described in connection with Figs. 10A through 10C), immediately readying the stapler for deployment of a second staple array.

[0078] Fig. 16 is a side view of an alternate embodiment of a multi-fire stapler or stapler device 110. The device includes a stapler head 112 mounted to an elongate shaft 114.

As will be appreciated from below, stapler head 112 is designed for reciprocal motion along an axis 123 between a compact, substantially cylindrical condition in which the head can be inserted into the patient's stomach transorally, and an expanded tissue-acquisition condition. The stapler head includes a staple housing or staple-holding member 116, which may be a replaceable staple cartridge, and an anvil or anvil member 118. The staple-holding member and anvil member having confronting tissue-contact surfaces 117, 119, respectively, that define a tissue-acquisition chamber 121, such as a vacuum chamber, therebetween.

[0079] The staple-holding member and anvil stapler head 112 are joined by coupling structure or linkages, such as arms 115 in Fig. 16, operable to accommodate movement of the staple-holding member and anvil member toward and away from one another. As can be appreciated from Fig. 16, the linkage arms will be substantially straight and parallel in the compact condition of the head, and extend progressively outwardly, as the staple-holding member and anvil are drawn toward one another, to capture a tissue fold in the tissue-acquisition chamber. The extending arms act to increase the areal dimension of the tissue-acquisition chamber, i.e., the area of the chamber normal to the reciproçal-motion axis of the device, such that an increasing-area of tissue fold is drawn into the chamber during a tissue-acquisition and stapling operation. These feature are described in greater detail in the in commonly owned Application No. 12/050,169, filed March 18, 2008, entitled ENDOSCOPIC STAPLING DEVICES AND METHODS, which is incorporated herein by reference. As detailed in that application, the device may further include a cutting element, e.g., hollow circular blade, that moves along the reciprocal axis of the device, independently of or coupled to the staple drive, to form a hole in the tissue after or during stapling.. Also as disclosed in the references application, the tissue-acquisition chamber in the device may be a vacuum chamber, where the device includes a vacuum port for applying a vacuum to the chamber, thus to draw tissue into the chamber. In this embodiment, a flexible sheath (not shown) extends between the staple-holding and anvil members, and the sheath has an opening on one side of the head through which tissue may be drawn into the chamber.

[0080] Like the staple housing of the first embodiment, cartridge 116 is a multi-fire unit configured to simultaneously fire an array of staples, and to automatically reload a subsequent array of staples ones the first array has been discharged. The staples in the array can be arranged in a variety of patterns, including but not limited to the square pattern shown in connection with the Fig. 16 embodiment.

[0081] Features of the cartridge or staple-holding member 116 will first be described with reference to the exploded views shown in Figs. 17 and 18. The cartridge includes a front

housing 120, middle housing 122 and a rear housing 124. The front housing 120 is positioned at the distal end of the cartridge and includes a plate 126 that contacts the tissue to be stapled during stapling. Spaced apart members 128 extend longitudinally from the plate 126 in a proximal direction. Each of the members 128 includes a circumferential channel 130. The plate 126 includes a central cutout 132 proportioned to receive middle housing 122.

[0082] Rear housing 124 has a plate 134 with a cutout 136 proportioned to receive the middle housing 122. Spaced apart members 138 extend longitudinally from the plate 134 in a distal direction. Members 138 have circumferential channels 140.

[0083] Middle housing 122 includes longitudinal sidewalls 142 proportioned to allow the middle housing 122 to slide into the central cutouts 132, 136 of the front and rear housings. Each of the sidewalls 142 has a longitudinally extending first channel 144 centrally positioned on the sidewall 142, and a longitudinally extending second channel 146 centrally positioned within the first channel 144.

[0084] As shown in Fig. 21A, in the assembled cartridge, the middle housing 122 extends between the cutouts of the front and rear housings. The longitudinally extending members 128 of the front housing 120 are disposed between the longitudinally extending members 138 of the rear housing such that the channels 130 of the walls 128 are aligned with the channels 140 of the walls 138, forming a continuous circumferential channel extending around the cartridge 116. As discussed in greater detail below, a compression band 152 (also see Fig. 18) is positioned in this circumferential channel.

[0085] When housings 120, 122, 124 are assembled, spaces between their various walls form chambers within which staples are positioned during use. Referring to Figs. 21A and 21B, rectangular U-shaped chambers 148 are disposed between each of the longitudinally extending members 128 and its neighboring members 138. Figs. 17 and 22 illustrate that a stack or collection of staples 30 is disposed in each of the chambers. A total of four such chambers 148 are shown, corresponding to four stacks of staples for the illustrated embodiment.

[0086] Each staple is positioned in its corresponding chamber with its legs disposed in the longitudinally extending branch of the chamber, and with the cross-member or back span of the staple in the laterally extending portion of the chamber. Each of the chambers 148 also houses rectangular V-shaped staple advancing element 150 adjacent to the radially outermost one of the staples 30.

[0087] Compression band 152 is disposed within the circumferential channel formed by the aligned channels 130, 140. The inner wall of the compression band is in contact with

the longitudinally extending legs of each of staple advancing elements 150 in the cartridge. The radially inward spring forces of the compression band bias the staple advancing elements 150, and thus all of the staples, in radially inward directions.

[0088] Referring again to Fig. 22, the longitudinal channels 144, 146 of the middle housing 122 form a chamber 154 with the walls bordering the cutouts in the front and rear housings 120, 124. The innermost staple 30a in each stack is biased into the chamber 154 by the radially inward forces of the compression band 152. A staple in the chamber 154 is in the ready position, ready for advancement from the cartridge into adjacent tissue.

[0089] Fig. 19 shows the front and rear housings aligned for insertion of the elements 128 of the front housing between the elements 138 of the rear housing. This figure best shows the positions of the ready position staple 30a, the remaining staples 30b-n, and the staple advancing element 150 for a given stack. As shown, the ready position staple 30a is biased against the wall of the middle housing 122 lining the first channel 144. The compression band 152 is removed for clarity.

[0090] A staple pusher assembly or staple driver 156 (Figs. 17 and 20) is provided for driving staples that are in the ready position from the cartridge into the tissue. Staple pusher assembly 156 includes pusher elements 158 slidable in a distal direction within corresponding ones of the chambers 154. Each pusher element has a plate 160 that slides through a corresponding one of the channels 144 of the middle housing (Fig. 19), to drive the ready position staple 30a biased into that channel. A rib 162 on the inwardly facing surface of the plate 160 slides through the associated channel 146 to maintain proper alignment of the pusher assembly 156 with the middle housing. Pusher assembly 156 may be advanceable by means of a hydraulically activated piston as described in commonly owned Application No. 12/050,169, filed March 18, 2008, entitled ENDOSCOPIC STAPLING DEVICES AND METHODS, or by other 30 means.

[0091] Figs. 23A through 23C are a sequence of cross-section views illustrating staple firing and subsequent reloading of the staple positions in preparation for an additional firing. Fig. 23A shows the cartridge prior to the firing of the first array of staples. As shown, the pusher assembly 156 is in the fully retracted or first position. The most radially inwardly positioned staples 30a of each staple stack 30 are disposed in the ready position in chamber 154. The second, third etc. staples 30 b-n of each stack are positioned in the chamber 148. In the Fig. 23A view, only the cross-pieces of the staples 30b-n are visible (in transverse cross-section) along with the corresponding portion of the U-shaped chamber 148. Fig. 23B shows the position of the pusher assembly 156 as it completes the process of pushing staples 30a

from the cartridge. The anvil, against which the legs of each staple fold, is not shown in Figs. 23A-C. As seen, movement of the staple driver in the pusher assembly from its first (Fig. 23A) to its second (Fig. 23B) simultaneously engages the four staples and forces them out of the staple-holding member. In actual operation, the staples are forced through a tissue fold and against the anvil surface, to form staples in the captured fold.

[0092] The pusher assembly is next retracted as shown in Fig. 23C, i.e., moved from its second position back to its first position. As this occurs, the radially inward forces of the compression band 152 against the staple advancing element 150 push the next staple in each stack into the ready position (i.e. in channel 144) vacated by the first staples to be driven. The stapler head may be repositioned to a second tissue area to be stapled, at which time the pusher assembly is again advanced to drive the second array of staples into the tissue. The process is repeated until the desired number of arrays has been applied to tissue, e.g., different selected tissue regions within the stomach, and/or until the staple sets have been exhausted. If additional staples are needed after the cartridge has been emptied of all staples, the stapler head is withdrawn from the patient, and the cartridge may be removed from the stapler and replaced with one filled with staples. Alternatively, the existing cartridge may be refilled by removing the compression band and the staple advancing elements, inserting staples in the chamber 154, and then replacing the staple advancing element and the compression band. The disclose multi-fire staple housings are useful in carrying out a number of procedures, including but not limited to stomach partitioning and/or the formation of stomach wall plications for use in retaining implants.

[0093] For example, the disclosed multi-fire housings may be employed in a stomach wall partitioning system. When an area of the stomach wall is drawn inwardly (bringing a two layer "pinch" or fold of tissue toward the stomach exterior), corresponding regions of serosal tissue on the exterior of the stomach are positioned facing one another. In stomach wall partitioning methods disclosed in commonly owned Application No. 12/119,329, filed May 12, 2008, entitled DEVICES AND METHODS FOR STOMACH PARTITIONING, two or more such areas or pinches of the stomach wall are engaged/grasped and drawn inwardly using instruments passed into the stomach via the mouth. The two or more pinches of tissue are held in complete or partial alignment with one another as staples or other fasteners are driven through the pinches, thus forming a four-layer tissue plication.

[0094] Multiple plications of this type may be used to induce weight loss by creating a barrier or narrowing within the stomach that will restrict the flow of food from the proximal stomach towards the distal stomach and/or that will effectively reduce stomach volume to

cause sensations of fullness after a patient eats relatively small quantities. A partition formed using plications might also be used as a treatment for GERD to create a shield between the stomach and esophagus that will minimize reflux.

[0095] Commonly owned Application No. 12/175,242, filed July 17, 2008, entitled ENDOSCOPIC IMPLANT SYSTEM AND METHOD and Application No. 12/050,169, filed March 18, 2008, entitled ENDOSCOPIC STAPLING DEVICES AND METHODS describe formation of plications by drawing a pinch of stomach wall tissue inwardly to form a tissue fold, and by then applying staple arrays or other fastening means to the tissue fold to retain the plication. Holes may be formed in the plications for receiving implants or anchors to which additional implants will be coupled.

[0096] The disclosed multi-fire staple housing will greatly facilitate these types of procedures by allowing serial formation of each of the required plications without necessitating removal of the stapler head from the stomach after formation of each plication. In other words, after a staple array is applied to tissue to create a plication, the staple head may be immediately repositioned and used to create second and subsequent plications, all without the need to remove the stapler head from the body for reloading or replacement with a fresh stapler. Thus, a stomach wall partition or a collection of plications may be formed in less time than was previously possible.

[0097] In addition to the staple arrangements disclosed above, alternative arrangements are suitable and can be used with feed mechanisms of the type disclosed above.

[0098] In one alternate staple arrangement, staples are formed into chains such that the legs are adjacent and the back spans do not touch. The arrangement would look like this: UUUUUUUU, although overlap of the staple elements is also possible. As one staple in the chain is driven from a ready position in the staple housing, and the driving member retracted, the next staple is moved into the ready position, with the feed motion primarily along the axis of the back span of the staple. Staples may be fired singly, or in multiples at the same time or at alternating times with one group (or single staple) firing while another group (or single staple) is reloading.

[0099] In a radial or "revolver" type staple arrangement, staples are arranged like spokes of a wheel, housed within a wheel, or on a belt, with the staple legs, and direction of driving generally parallel to the axis of the wheel (like the bullets in the chamber of a revolver). As an example, 3 of the 12 staples (either equally spaced about the ring or not) could be advanced, then the driving member is retracted and either the driving member indexed to the next three staples, or the staple magazine is indexed such that the next three

staples are aligned with the driver. This motion could continue for 4 total firings of 3 staples each. In a modified, ferris wheel type arrangement, the staples are oriented with the staple legs perpendicular to the axis of the wheel, or in a non-circular belt. In this case, the driver would drive staples toward the outside from the inside, or toward the inside from the outside of the wheel or belt.

[00100] Other embodiments use flat nested arrangements of staples. For example, a low profile way of storing the staples would be to lay them flat on each other with each one slightly in front of the previous one, like dominoes after they have fallen. In this case, a method of tilting up the staple to be driven would be used. Double forming without tilting would also make this possible. In this instance, staples would be pushed forward and bent down, then crushed to the traditional B shape.

[00101] In another arrangement, the array or magazine of staples consists of a chain of groups of staples. The staples are housed in a link of the chain which is designed to interface with the driving member. When a link of the chain, with one to 5 or more staples is advanced to the driver, those staples may be driven. Upon retraction of the driver, the chain is advanced and the spent link is pushed beyond the driving zone and a new link is advanced into the driving zone. The spent links could move to a containment area, or proceed out of the device. Similarly, the loaded links could be housed in a containment area, or extend beyond the envelope of the device. If the material of the chain in this example, or any mentioned elsewhere in this description, were biocompatible, or bioabsorbable, the links of the chain could be discarded in the lumen or incorporated into the staple line such that no, or less, spent chain material required post-firing management.

[00102] One embodiment of a stapler employing this concept will next be described. Fig. 24 illustrates a stapler head 210 including a staple-holding housing or staple-holding member 212 and an anvil or anvil member 214. Three staple cartridges 216a-c are shown. Cartridge 216a, shown coupled to the housing 212 and facing anvil 214, contains a plurality of staples and is position for staple delivery, i.e. to receive a driver that will fire the staples from the cartridge into tissue disposed between the cartridge and anvil. Cartridge 216b, which has already been fired, is in the background. Another cartridge 216b is in the foreground, waiting to be advanced into position between the cartridge and anvil for reloading of the stapler. The cartridges 216a-c are flexibly linked together, as shown. More generally, the cartridges may be supported for successive loading into the cartridge chamber of the staple-holding member as a string of cartridges, such as by a flexible tether or pivoting joint connection joining the exit end of one cartridge to the entry end of another. Alternatively, the

cartridges could be housed in chamber for successive passage from the chamber into the staple-holding member. The inter-cartridge connections or housing form means for supporting the cartridge for successive loading into and release from the staple-holding member.

[00103] Fig. 25 shows a close-up view of the cartridge 216a prior to its advancement into the housing 212. Wings 218 at the end of the cartridge will flex inward as the cartridge passes through the anvil extensions above the anvil pivot 220. Once they are past the anvil extensions, they spring outward and when stapling forces are applied to drive staples from the cartridge towards the anvil, the cartridge will slide backward slightly and the wings will push on the anvil extensions above the anvil pivot. This will help to keep the anvil aligned with the cartridge face, even as stapling forces push them apart.

[00104] As best shown in Fig. 25, each cartridge includes a plurality of slots 222 proportioned to receive a plurality of staples. Caps 224 are positioned above the back spans of staples in the slots. Caps 224 are shown in only two of the slots 222 in Fig. 25. Each cap 224 includes a sloped surface 226. During use, each of the four slots 222 may be filled with staples and caps 224.

[00105] Referring to Fig. 26A, a driving wedge 232 has four wedge-shaped plates (only one of which is visible), each extending into one of the slots 222. A cable pull or other mechanism is provided for advancing the driving wedge longitudinally through the housing 210 (from left to right in the illustrated drawings) so that the wedge-shaped plates move through the slots 222. The wedge-shaped plates are positioned such that when they travel in the slots, they contact the caps 224 corresponding to the various staples S (Figs. 26A - E) within a given slot 222 in a manner similar to that described in connection with Figs. 9B - 9E, thereby driving the staples into tissue positioned between the housing and anvil.

[00106] Spring 228 is disposed in a channel in the housing 212 and is configured such that it is compressed as the driving wedge 232 is moved by the user actuating a cable or other force transfer element. For example, the wedge 232 might be coupled to a cable extending through the spring 228 and attached to cap 234 on the spring 228 such that as the wedge moves to the 5 right in Fig. 26A, the cable pulls the cap 234 to the left to compress the spring. A second spring 230 is attached to the driving wedge 232 and is compressed by a lever 236 riding in a groove 238 (Fig. 25) in the cartridge. This groove 238 increases in depth at the end of the wedge's stroke, thus providing a notch 240 for the lever 236 to fall into at the end of its travel.

[00107] Fig. 26A shows the staple head 210 after staples have been fired from cartridge 216b and after cartridge 216a has been moved into the housing such that its staples are in staple delivery positions ready for firing. Figs. 26A - 26C show stages of staple deployment as the wedge 232 is drawn over the staple driving elements or caps 234. The wedge 232 moves from the home position (Fig. 26A) through the cartridge to deploy the staples through the tissue, such that their legs fold against the anvil 214. As the wedge advances, the spring 228 is compressed. As the wedge reaches the end of its travel, lever 236 pivots into the notch 240 as shown in Fig. 26D. When the user stops pulling on the wedge (e.g. by releasing a pull cable), the loaded return spring 228 will unload, driving the wedge 232 and lever 236 towards the home position, which is towards the left in the Fig. 26A-E drawings. The lever 236 pushes against wall 242 of the groove 238, thus driving the spent cartridge 216a out of the stapler (Fig. 26E) while drawing in the next loaded cartridge 216b that is coupled to the cartridge 216a. The lever thus forms a release mechanism for releasing a cartridge from the staple-holding member after the cartridge staples have been ejected.

[00108] The stapler is repositioned and the sequence is repeated until all the cartridges have been fired, or until stapling is complete.

[00109] It may be advantageous to maintain a level of mechanical simplicity comparable to currently produced linear staplers, but enable multi-fire capability without the need to withdraw the stapler from the patient. In this design, the spent cartridge is made to be ejected and be dropped in place, or be tethered or otherwise connected to the stapler or to the next cartridge to be loaded into the stapler. Loading would be accomplished with tools already in the patient, or with additional mechanisms within the tool itself, which would form or act as a conveyor of, or conduit for, new cartridges being advanced to the stapler head.

[00110] The above groupings are not exclusive and, for example, radial driver or magazine motion could be combined with stacked, flat nested, or chained staple arrangements.

[00111] It should be recognized that a number of variations of the above-identified embodiments will be obvious to one of ordinary skill in the art in view of the foregoing description. Moreover, features of the disclosed embodiments may be combined with one another and with other features (including those taught in the prior applications referenced herein) in varying ways to produce additional embodiments. Accordingly, the invention is not to be limited by those specific embodiments and methods of the present invention shown and described herein. The applications and methods listed are not limited to the treatment of diseases or procedures listed. Modifications of the above described methods and tools and

variations of this invention that are obvious to those of skill in the art are intended to be within the scope of this disclosure.

[00112] Any and all patents, patent applications and printed publications referred to above, including those relied upon for purposes of priority, are incorporated herein by reference.

IT IS CLAIMED:

1. A device for acquiring and stapling multiple tissue regions within a subject's stomach, by introducing the device transorally into the subject's stomach, said device comprising, in operative condition,

(a) a multi-fire staple head designed for reciprocal motion along an axis between a compact condition in which the head can be inserted into the stomach transorally and an expanded tissue-acquisition condition,

(b) a shaft to which the head is attached and by which the head in its compact condition can be introduced transorally into the stomach, and

(c) a tissue-acquisition device for acquiring tissue within the stomach,

said multi-fire staple head comprising

(i) a staple-holding member having a plurality of staple-holding chambers arrayed in a pattern about said axis, each chamber terminating at a staple-ready position, a plurality of staples held within each chamber, with one of the staples in each chamber being positioned at the staple-ready position in that chamber, and a staple driver for engaging those staples in the staple-ready position within each chamber and driving the engaged staples across the face plate and out of the staple-holding member, when the staple driver is moved from a first to a second position, wherein movement of the staple driver from its second to its first position results in the advance of a new staple in each chamber to a staple-ready position,

(ii) an anvil member,

(iii) a tissue-capture chamber defined between confronting surfaces of the staple-holding member and the anvil member, and

(iv) structure coupling the staple-holding and anvil members for reciprocal motion along said axis toward and away from one another between said compact condition and said expanded condition at which the tissue-acquisition chamber has an expanded areal dimension and a tissue fold within the chamber is captured between the members.

2. The device of claim 1, wherein said plurality of staple-holding chambers are arranged symmetrically in a non-linear pattern about said axis.

3. The device of claim 1, wherein said plurality of staple-holding chambers include four chambers arranged in a square pattern about said axis.

4. The device of claim 2, wherein said head further includes a cutting element which moves along said axis, independently of or coupled to the staple driver, to form a hole in a tissue fold being stapled.

5. The device of claim 1, wherein said tissue-acquisition device is a vacuum chamber contained within the stapler head, and the device further includes a vacuum port for applying a vacuum to the chamber, thus to draw tissue into the chamber.

6. The device of claim 1, wherein said tissue-acquisition device includes a mechanical grasper for engaging a tissue fold and drawing the engaged fold into the tissue-capture chamber.

7. A method for acquiring and stapling multiple tissue regions within a subject's stomach, comprising

(a) transorally introducing into the patient's stomach a multi-fire-stapling device and a tissue-acquisition device,

(b) manipulating the tissue-acquisition device to engage stomach tissue at a selected stomach region;

(c) drawing the engaged tissue into a tissue-acquisition chamber in said stapling device, thus forming a tissue fold within said chamber,

(d) activating said stapling device to place a plurality of staples in the fold within the chamber,

(e) releasing the stapled tissue fold formed in step (d), and

(f) without having to withdraw the stapling or acquisition devices from the stomach, repeating step (a)-(e) until a desired number of stapled tissue folds are formed within the subject's stomach.

8. The method of claim 7, wherein the multi-fire stapling device introduced into the stomach is designed for reciprocal motion along an axis between a compact condition in which the head can be inserted into the stomach transorally and an expanded tissue-acquisition condition.

9. The method of claim 8, wherein , said multi-fire staple head comprises

(i) a staple-holding member having a plurality of staple-holding chambers arrayed in a pattern about said axis, each chamber terminating at a staple-ready position, a plurality of staples held within each chamber, with one of the staples in each chamber being positioned at the staple-ready position in that chamber, and a staple driver for engaging those staples in the staple-ready position within each chamber and driving the engaged staples across the face plate and out of the staple-holding member, when the staple driver is moved from a first to a second position, wherein movement of the staple driver from its second to its first position results in the advance of a new staple in each chamber to a staple-ready position,

(ii) an anvil member,

(iii) a tissue-capture chamber defined between confronting surfaces of the staple-holding member and anvil member, and

(iv) structure coupling the staple-holding and anvil members for reciprocal motion along said axis toward and away from one another between said compact condition and said expanded condition at which the tissue-acquisition chamber is also expanded and a tissue fold within the chamber is supported between the staple-holding and anvil-members.

10. The method of claim 9, wherein activating step (d) is operable to form a square array of four staples in the captured tissue fold.

11. The method of claim 9, wherein said head further includes a cutting element that moves along said axis independently of or coupled to the staple driver, and stapling step (d) includes forming a hole in the tissue fold being stapled.

12. The method of claim 9, wherein the tissue-acquisition device includes a vacuum chamber in the stapler head, step (b) includes manipulating the stapler head to place the vacuum chamber against a tissue region to be acquired, and applying a vacuum to the chamber to engage said tissue region, and step (c) includes continuing to apply said vacuum while moving the stapling head to its expanded condition, to draw engaged tissue into the vacuum chamber.

13. The method of claim 7, wherein said tissue-acquisition device includes a mechanical grasper for engaging a tissue fold, step (b) includes manipulating the grasper to engage a tissue region to be acquired, and step (c) moving the grasper and engaged tissue region into the tissue-acquisition chamber of the stapling device.

14. A device for stapling multiple tissue regions comprising, in operative condition,

(a) a staple-holding member having a plurality of rows of plural staple-holding chambers, and at least one staple held within each chamber, with at least one staple in each chamber being positioned at a staple-ready position in that chamber,

(b) an anvil member that is movable with respect to the staple holding member, for stapling tissue supported between the staple-holding member and anvil, and

(c) a staple driver carried on said staple holding member for movement from a first to a second position at which those staples in the staple-ready position within a selected row of staple-holding chambers are advanced from the staple-holding member against the anvil member, to form a linear array of staples through tissue supported between the two members.

15. The device of claim 14, which includes a separate staple driver for each linear array of chambers.

16. The device of claim 15, wherein each staple driver includes a staple-engaging wedge that travels along a row of staple in a linear array, successively engaging those staples in a staple-ready position within a single linear array of chambers.

17. The device of claim 15, wherein the rows of staple chambers are disposed on a rotating barrel, for successive rotation to row positions at which a selected row is positioned adjacent said anvil, such that activation of a fixed-position staple driver is effective to eject staples from the chambers in that row against the anvil, thereby stapling tissue captured between the chamber row and anvil.

18. A device for performing multiple stapling operations within a hollow organ of a subject, comprising,

(a) a staple-holding member having a cartridge housing and a staple driver that is movable within the member between first and second positions,

(b) an anvil member mounted on the staple-holding member for pivoting thereon, for movement toward and away from a stapling position, and

(c) a plurality of staple cartridges, each having (i) a plurality of staples, (ii) at least one driver slot through which the staple driver can be moved from its first to its second positions to eject one or more staples from the cartridge, when the two members are moved to

their stapling position, and (iii) locking structure that locks a cartridge within the cartridge housing, when that cartridge is introduced into the staple-holding member,

(d) a release mechanism associated with the staple-holding member for releasing a cartridge from the staple-holding member after the cartridge staples have been ejected, and

(e) means for supporting the cartridges for successive loading into and release from the staple-holding member.

19. The device of claim 18, wherein said release mechanism includes a spring-loaded staple driver lever that acts to push a cartridge from the staple-holding member after the staple driver has been moved, against a spring bias, to its second position, to eject staples from the cartridge.

20. The device of claim 18, wherein the staple driver includes a staple-engaging wedge that travels along a row of staples in a linear array, successively engaging cartridge staples.

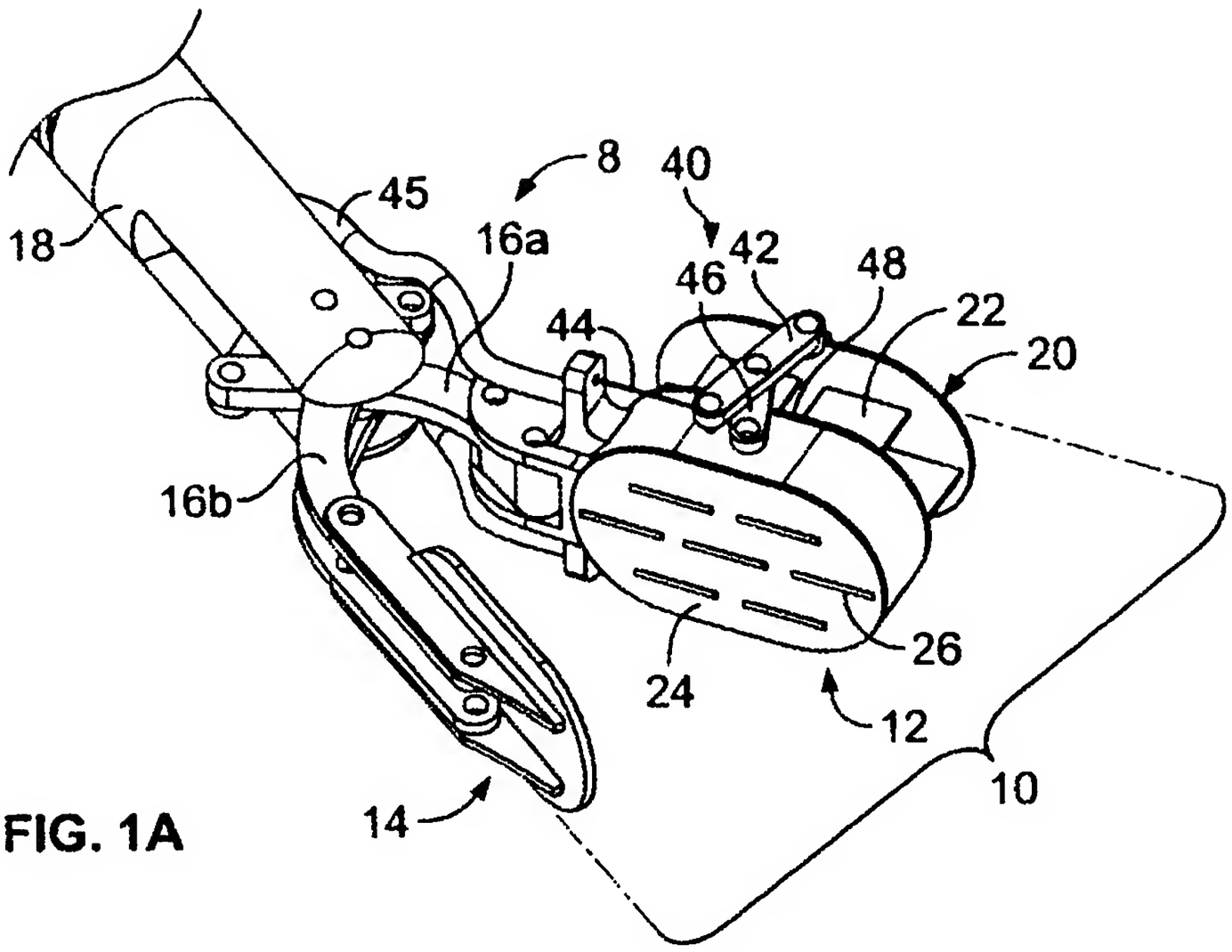

FIG. 1A

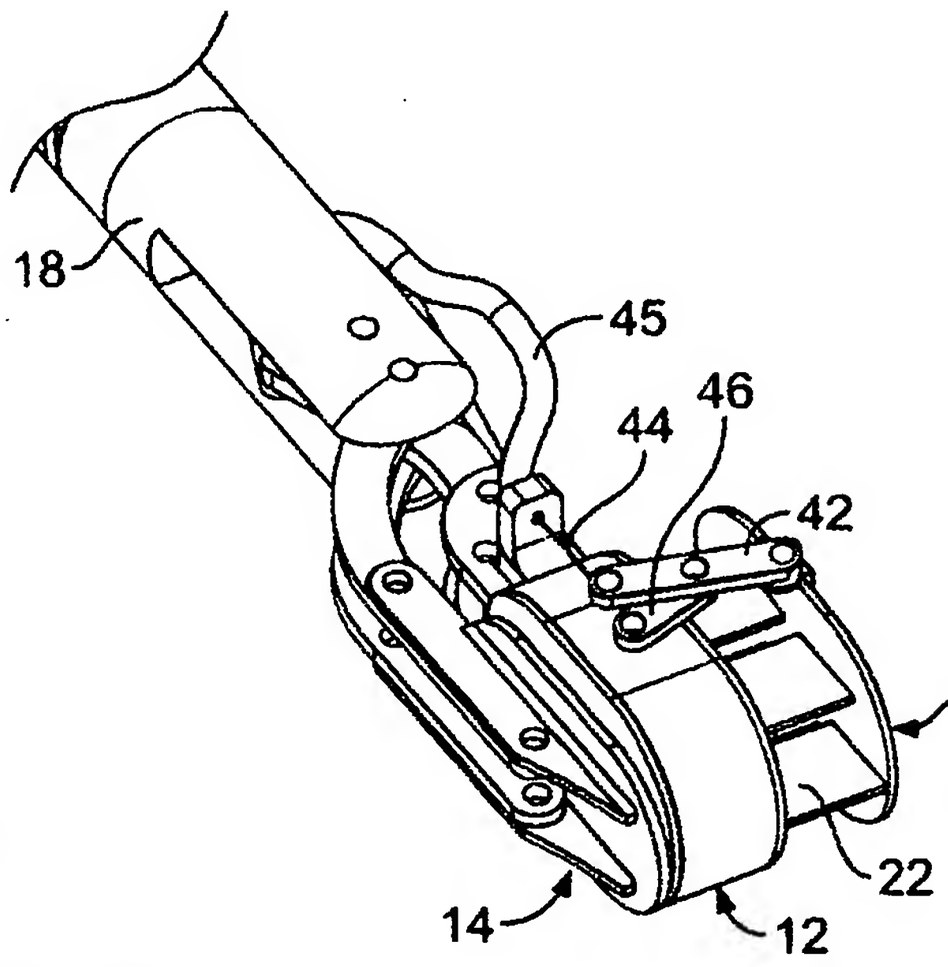

FIG. 1B

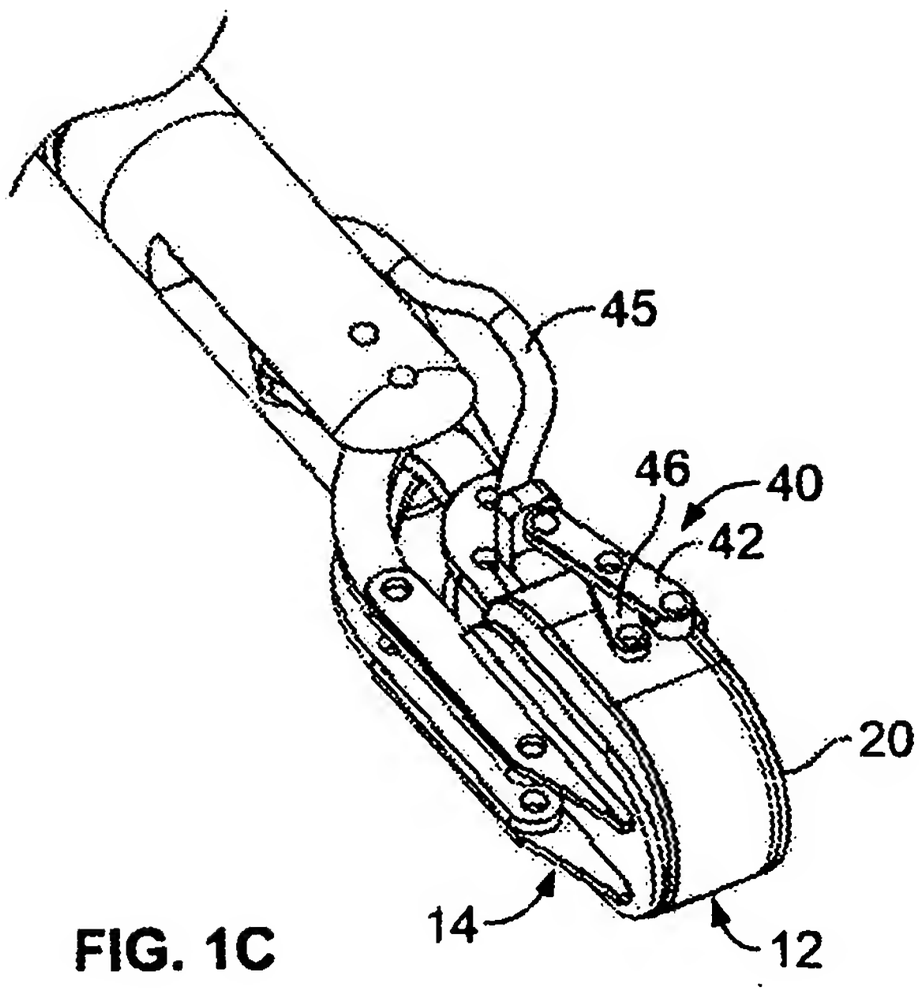

FIG. 1C

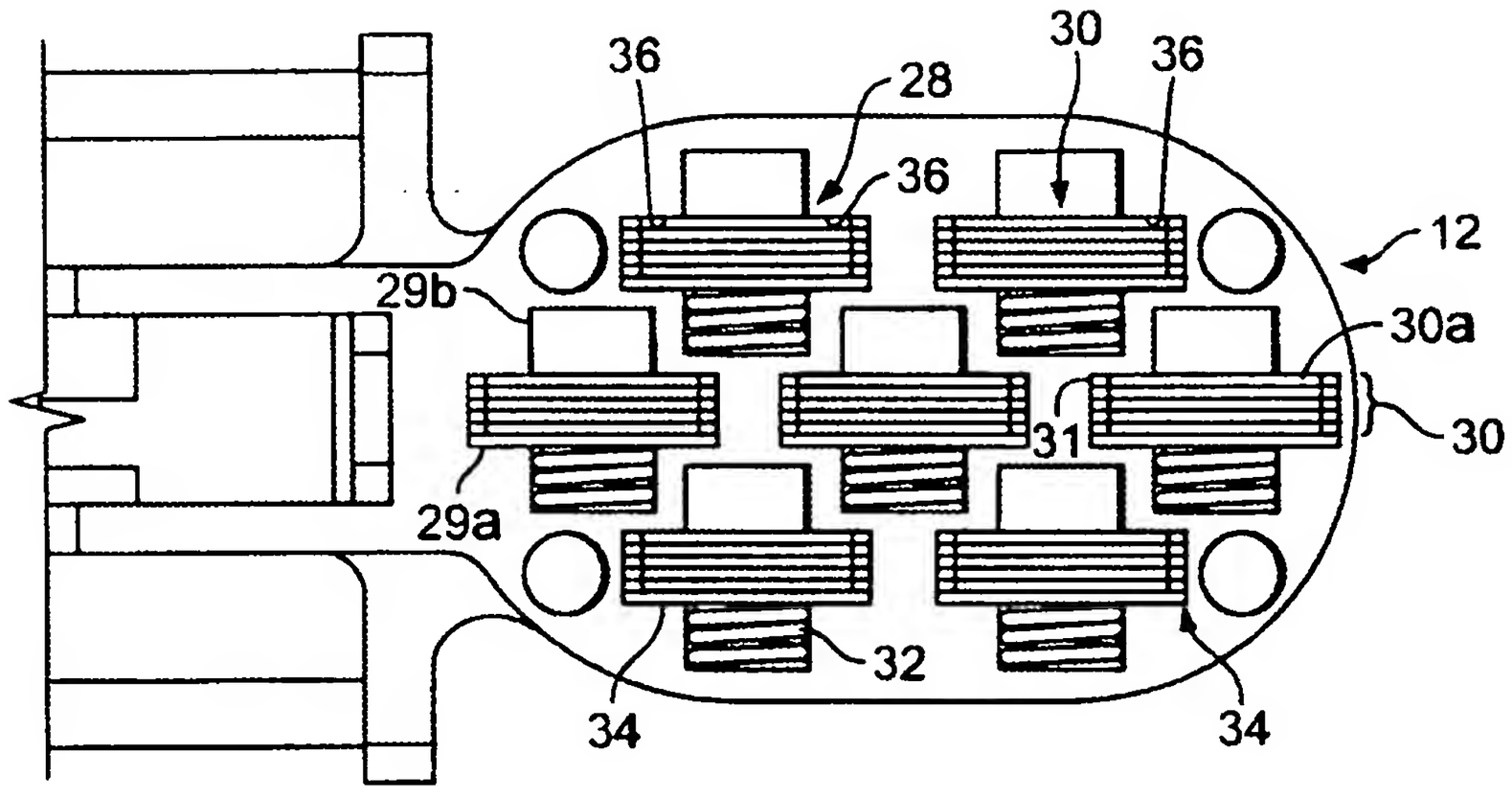

FIG. 2

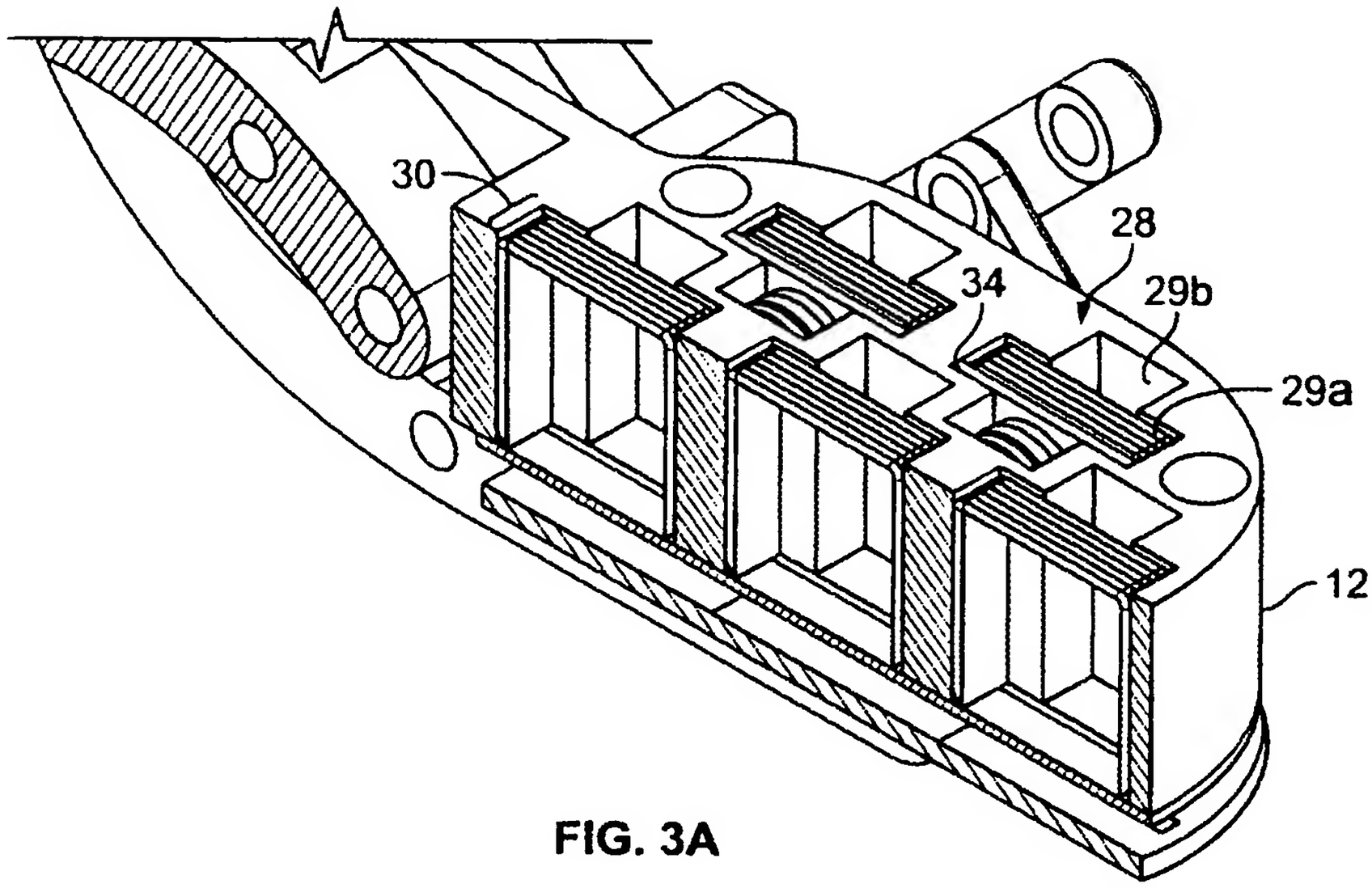

FIG. 3A

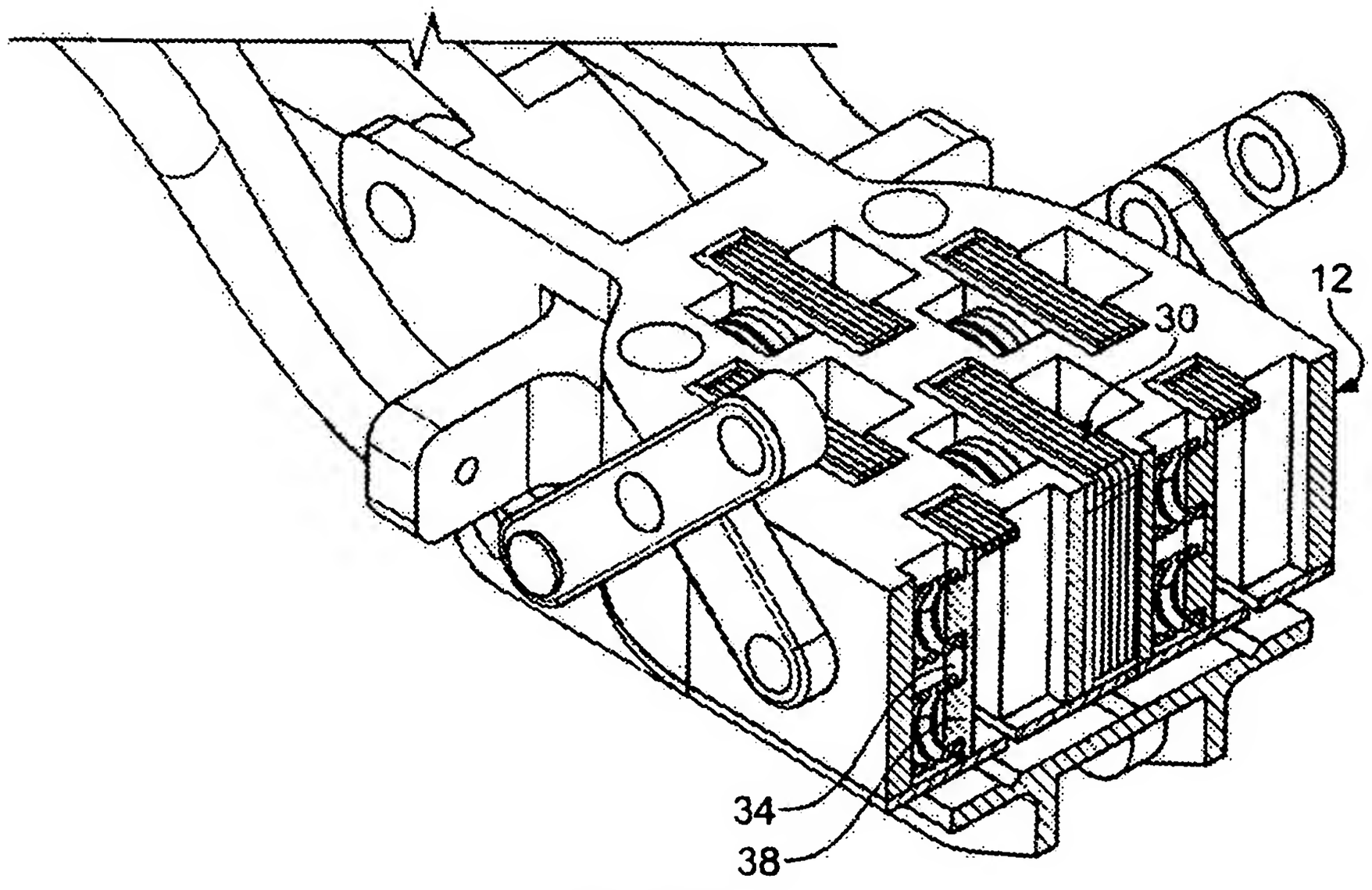

FIG. 3B

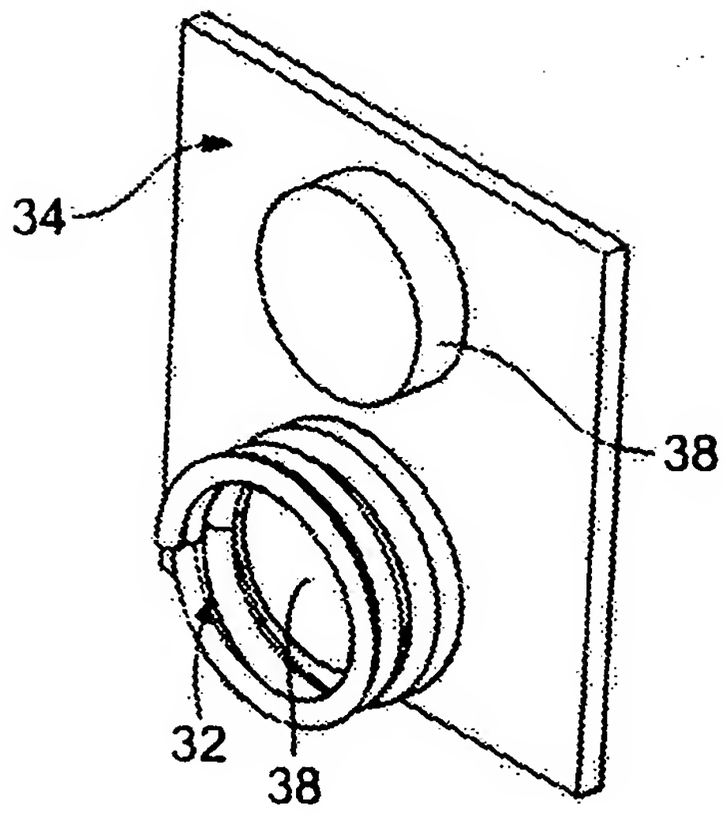

FIG. 4

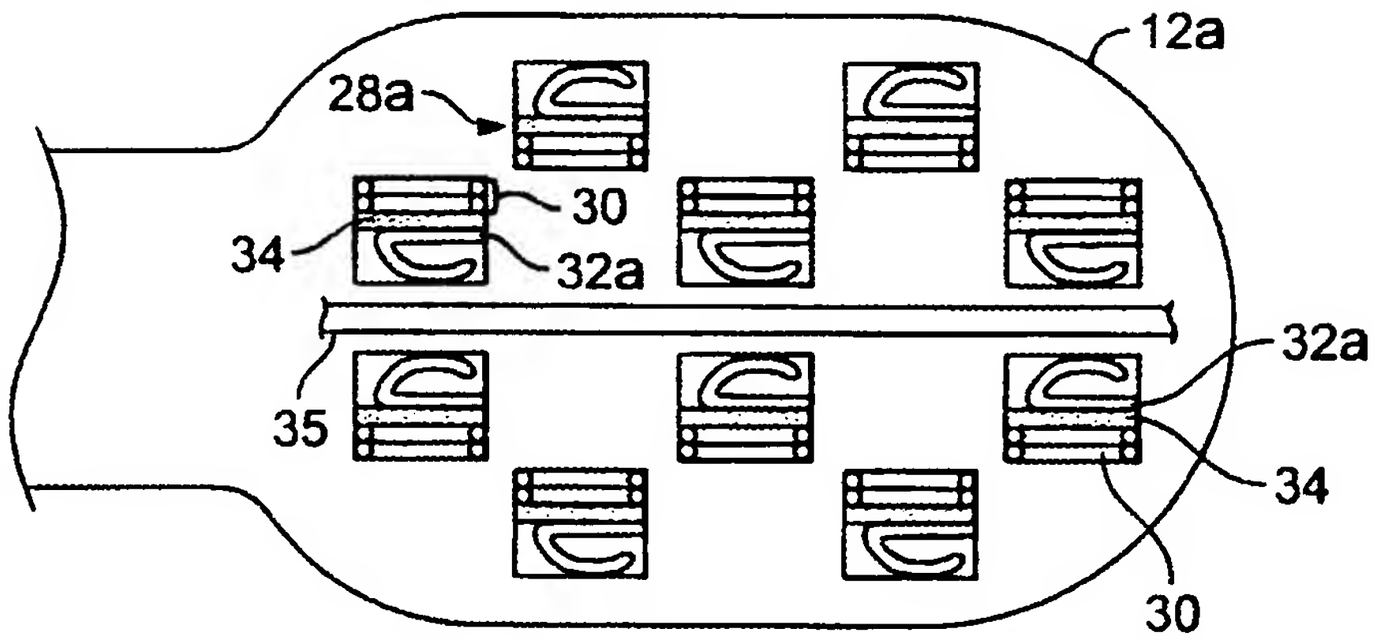

FIG. 5A

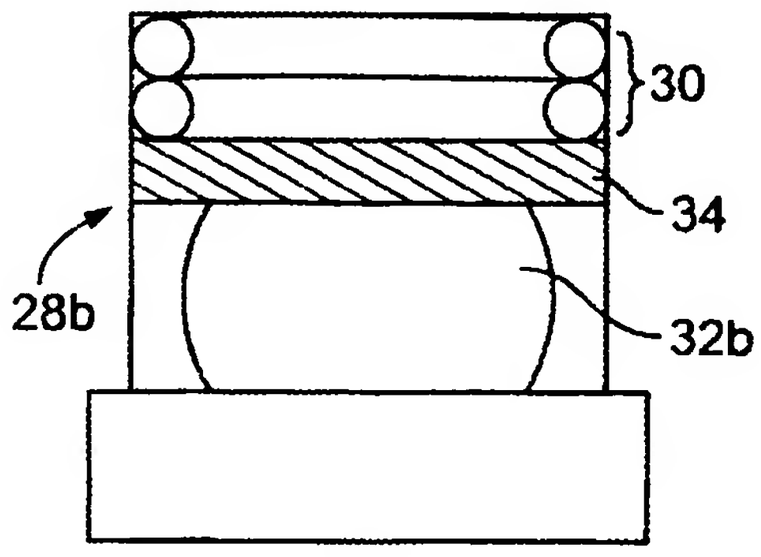

FIG. 5B

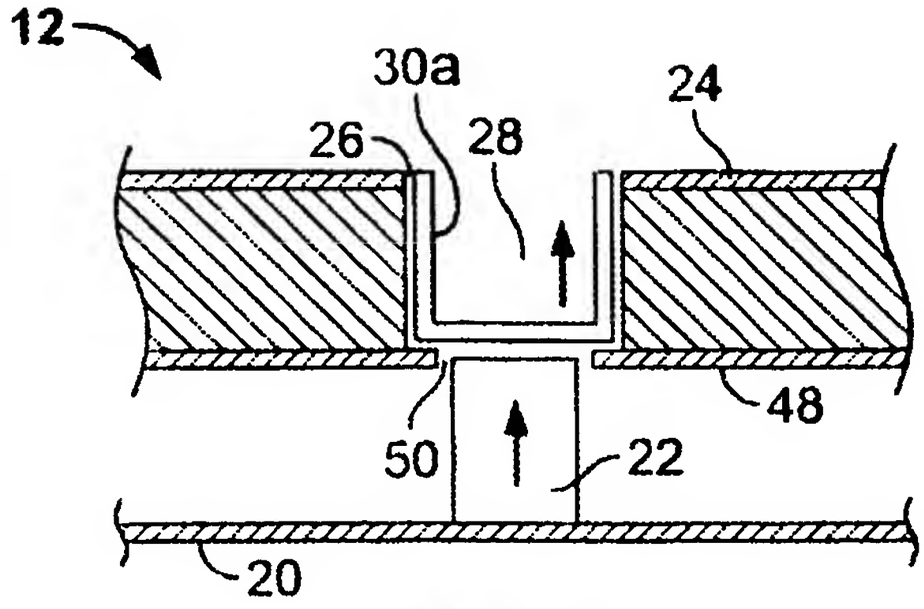

FIG. 6

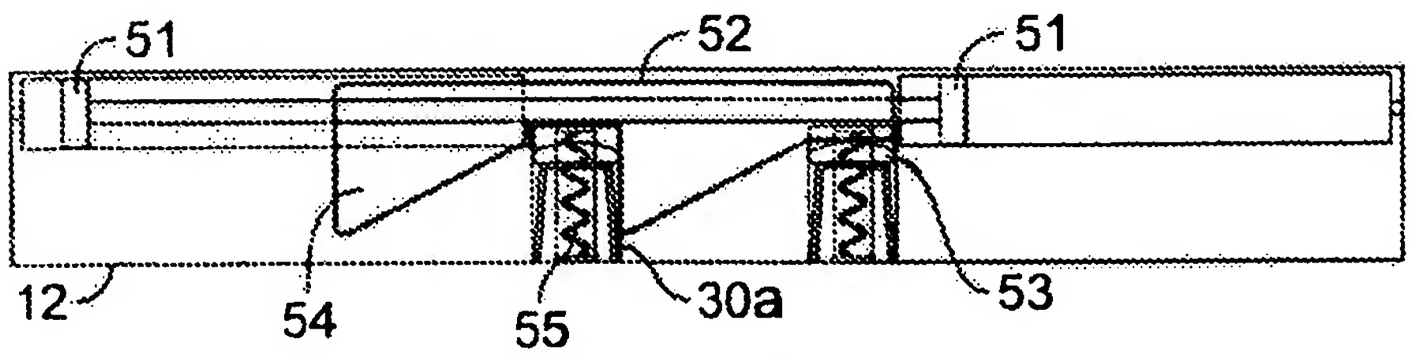

FIG. 7A

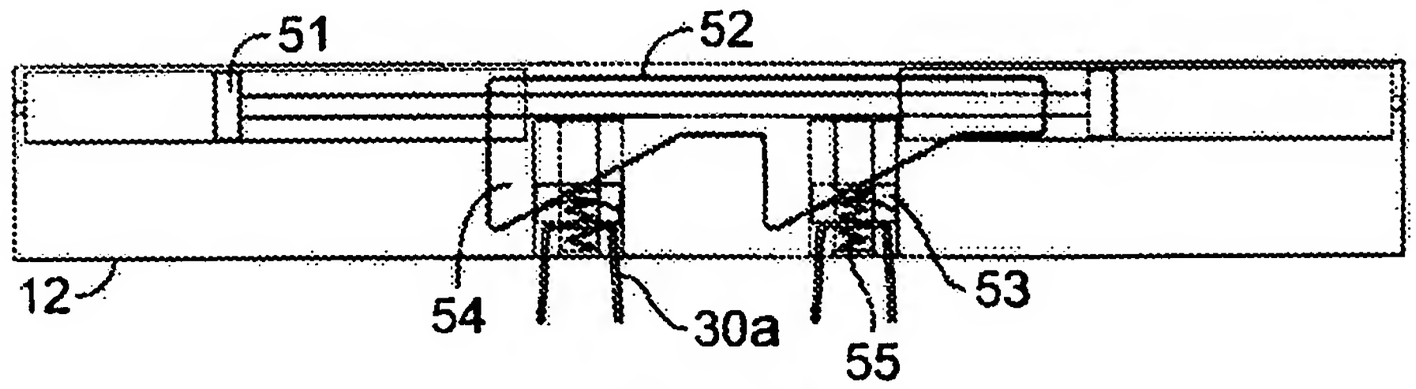

FIG. 7B

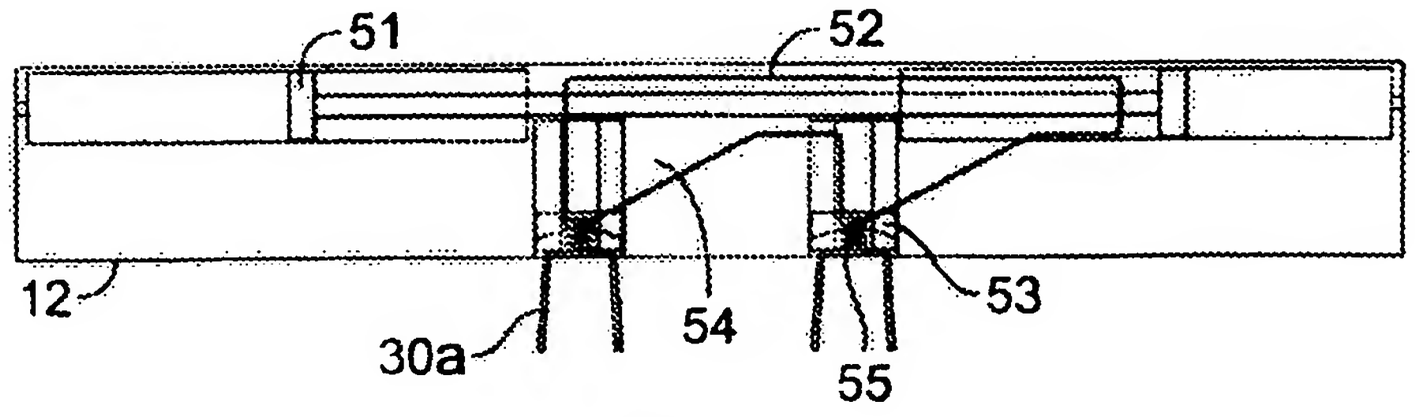

FIG. 7C

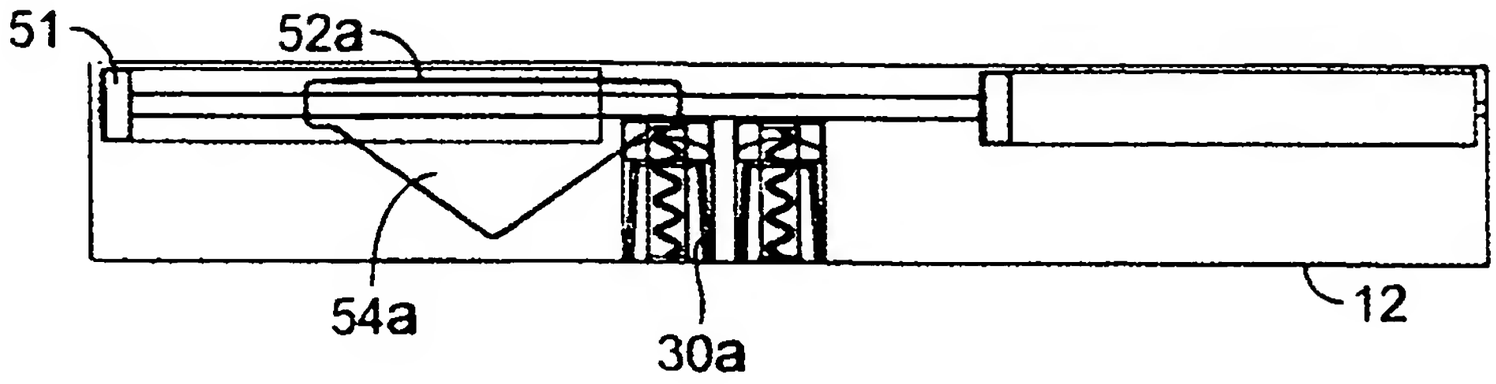

FIG. 8A

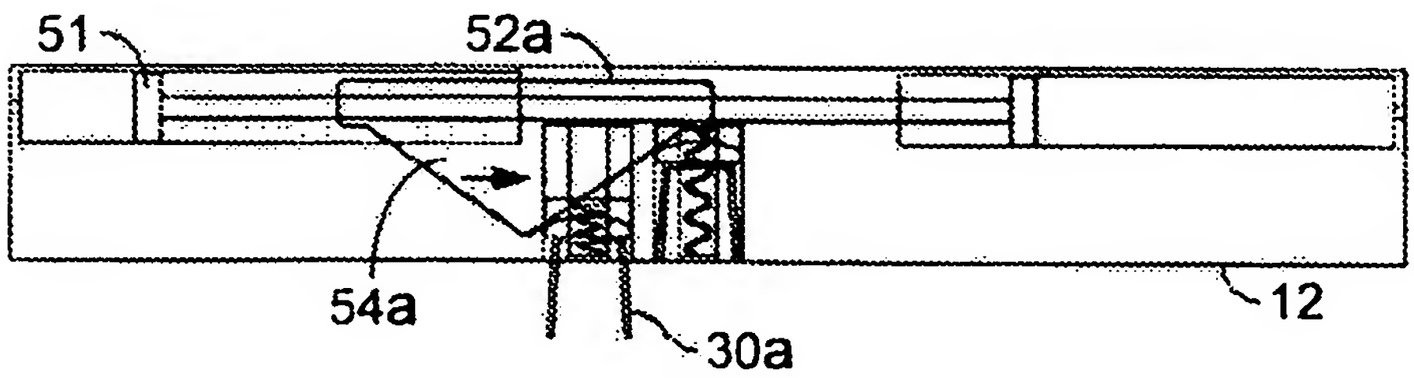

FIG. 8B

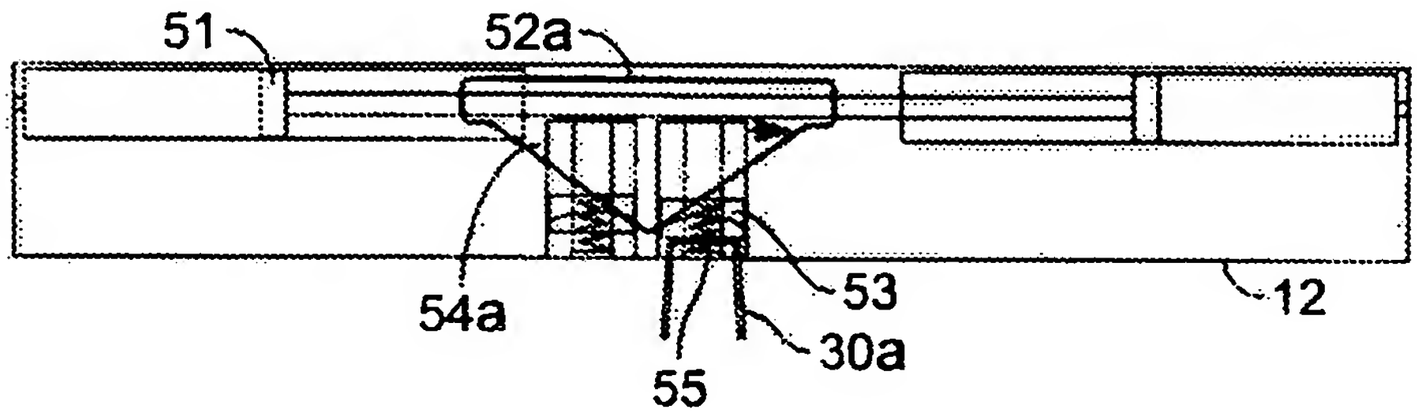

FIG. 8C

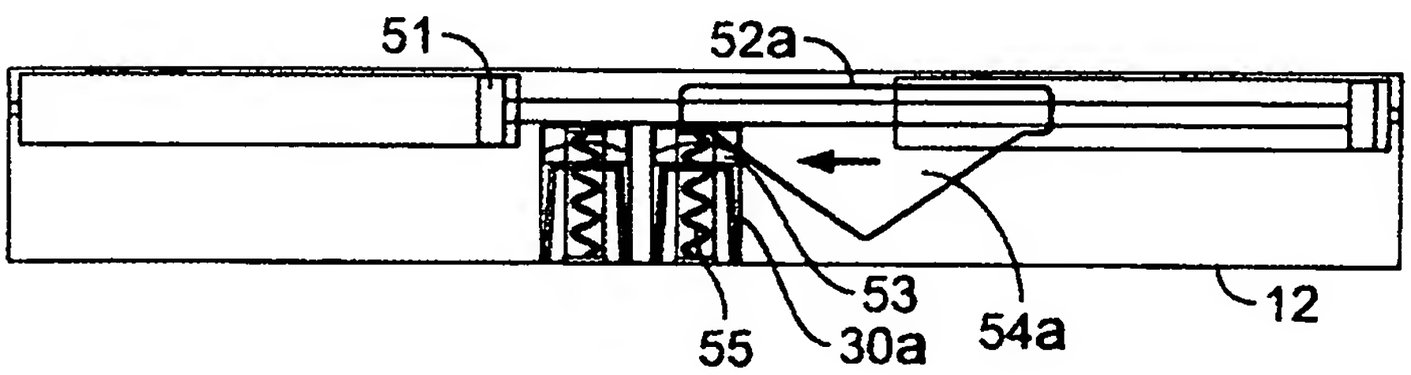

FIG. 8D

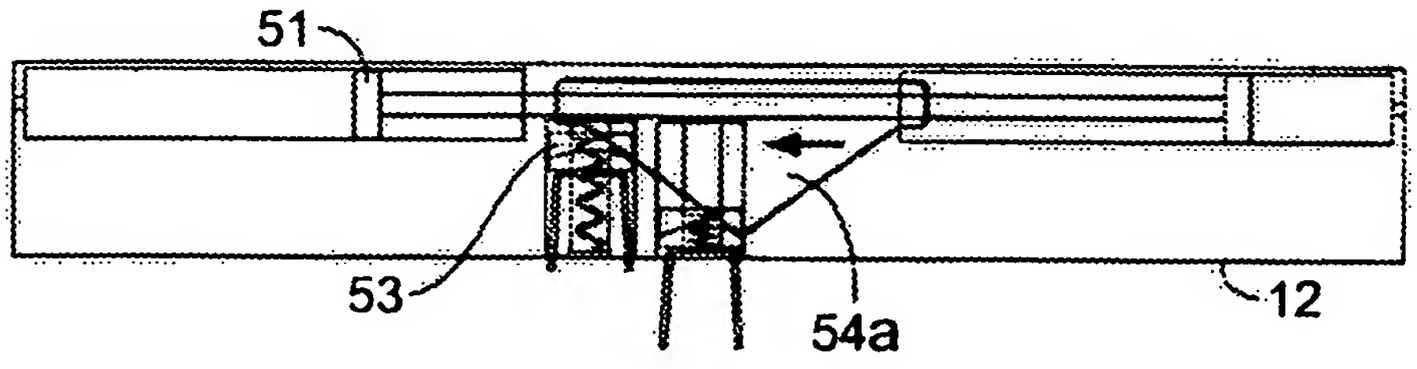

FIG. 8E

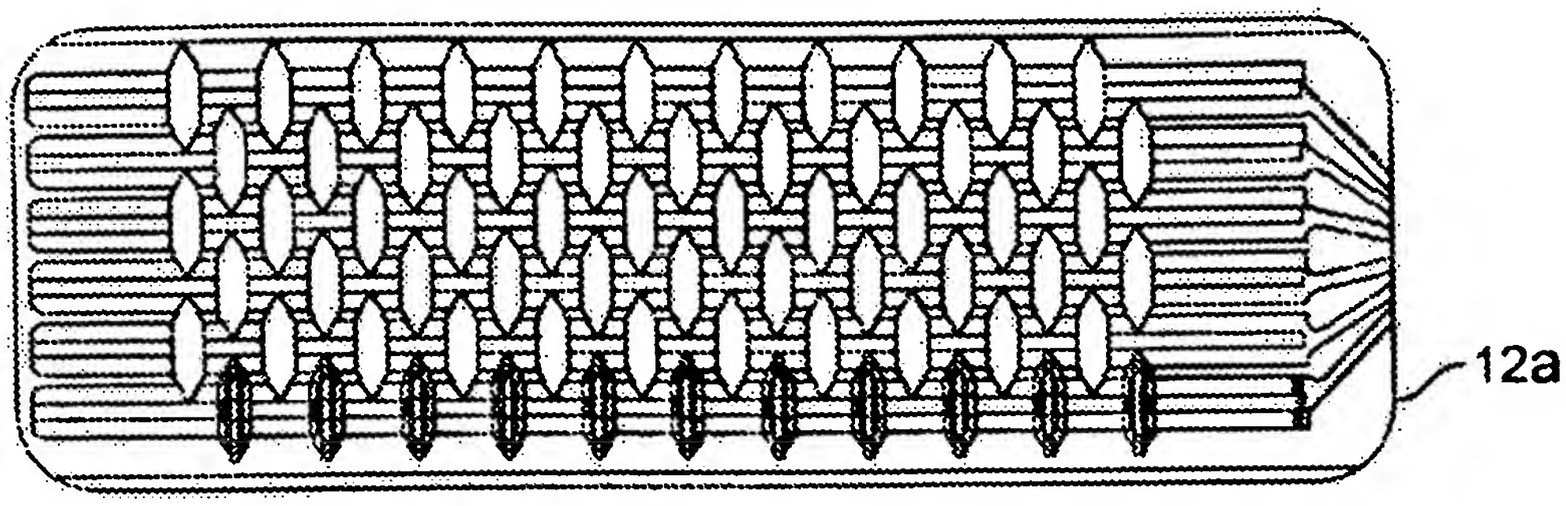

FIG. 9A

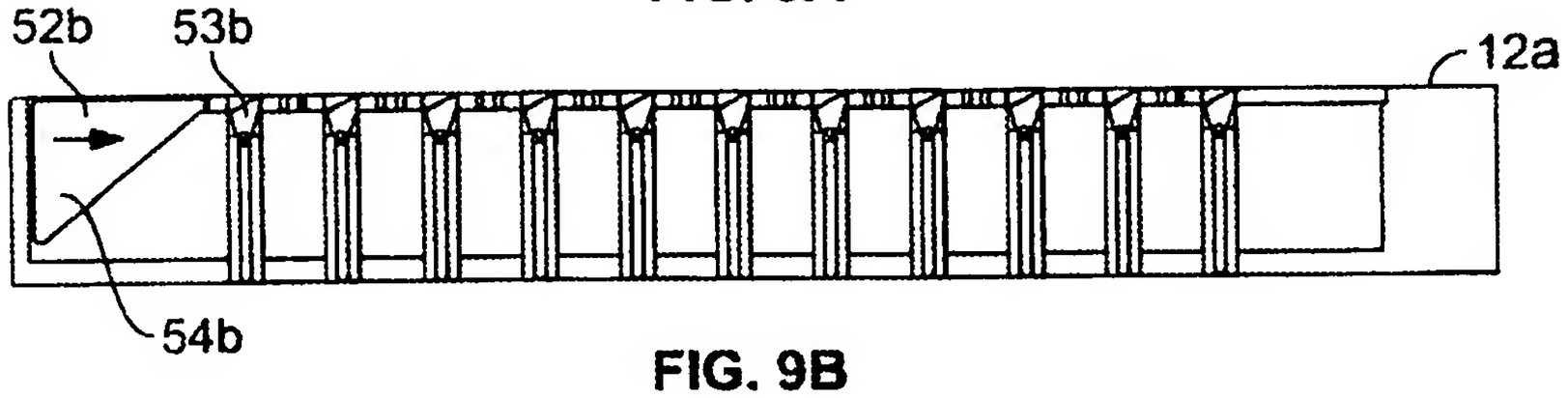

FIG. 9B

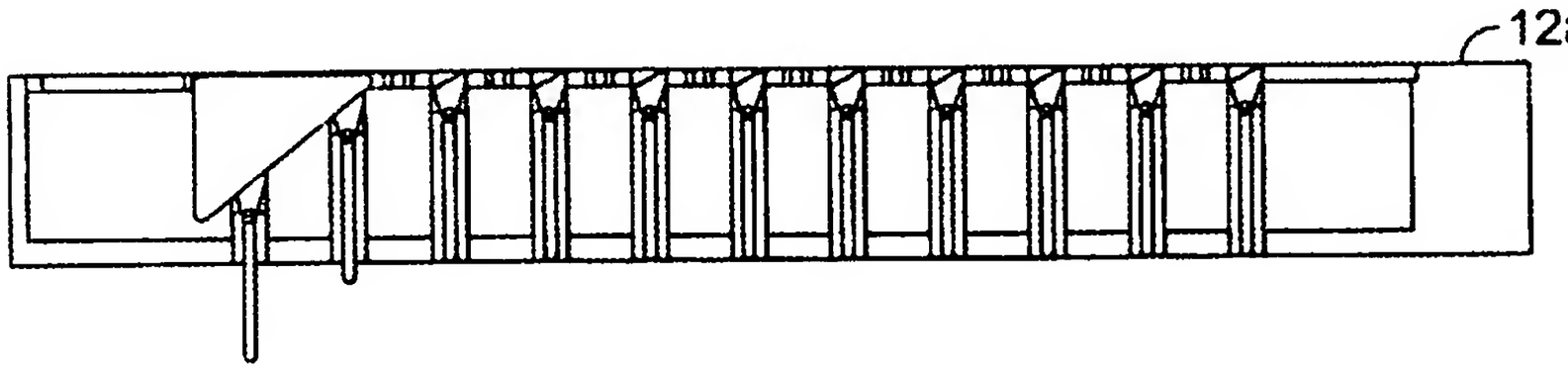

FIG. 9C

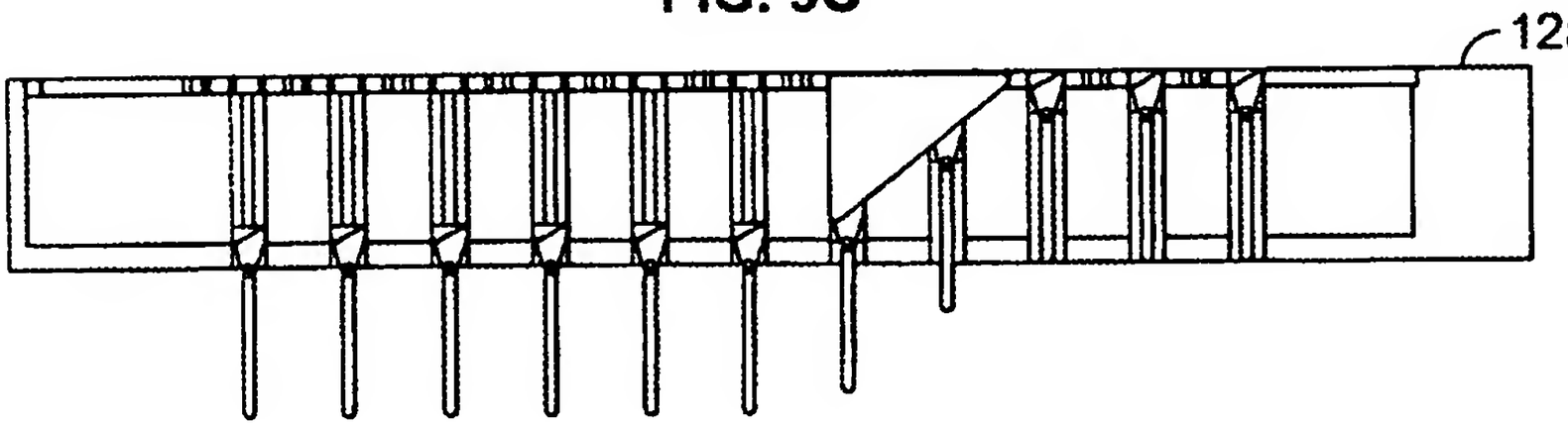

FIG. 9D

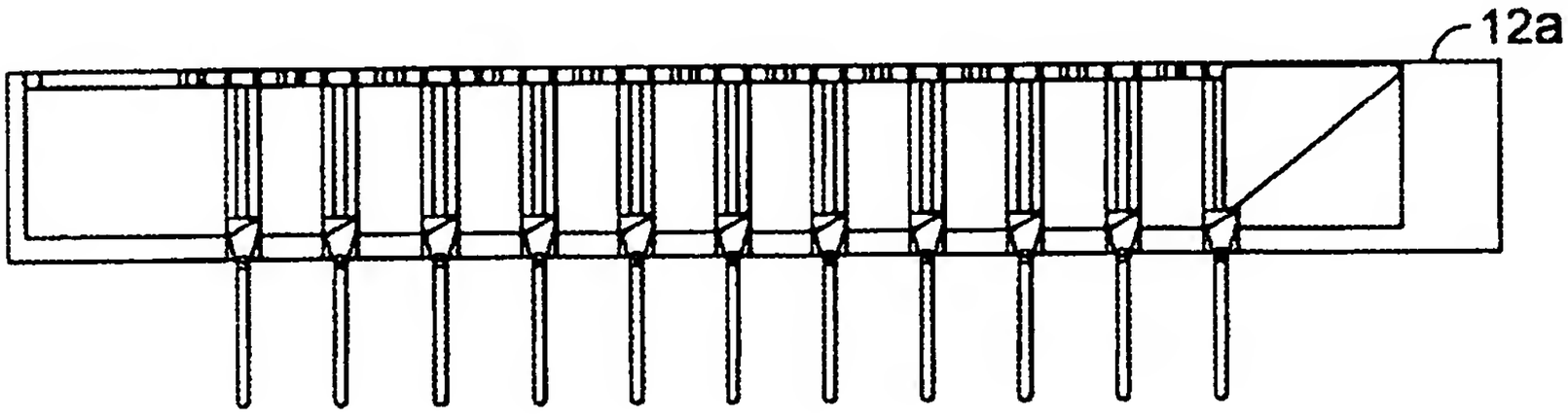

FIG. 9E

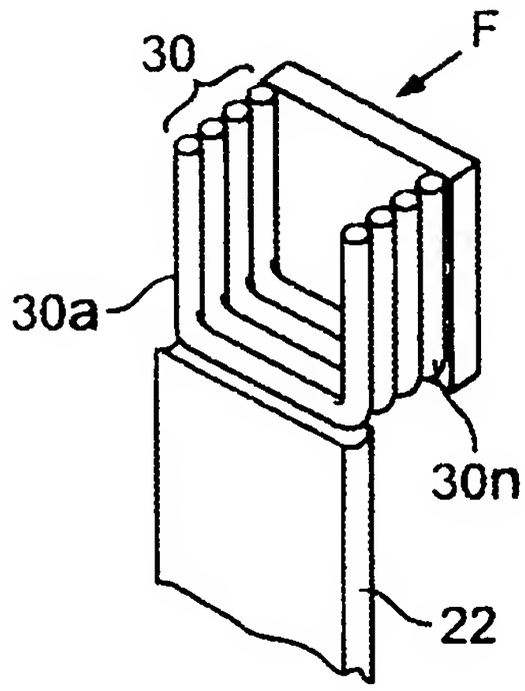

FIG. 10A

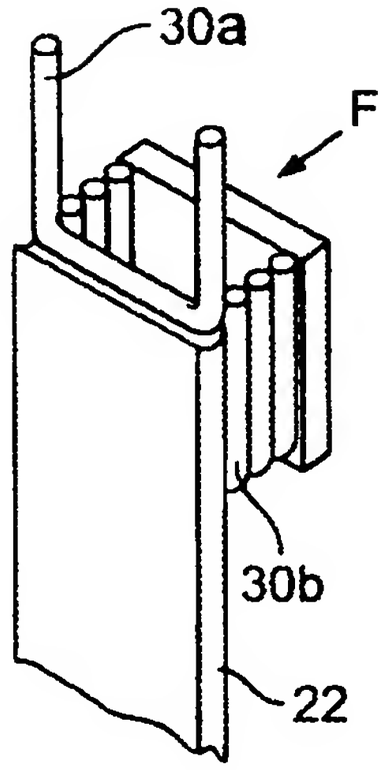

FIG. 10B

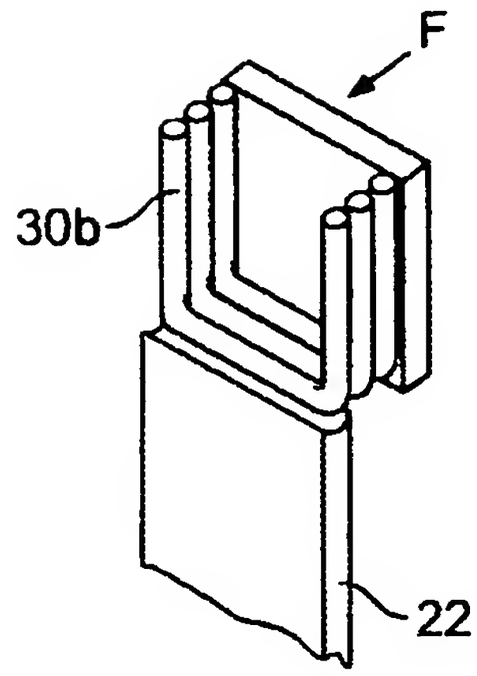

FIG. 10C

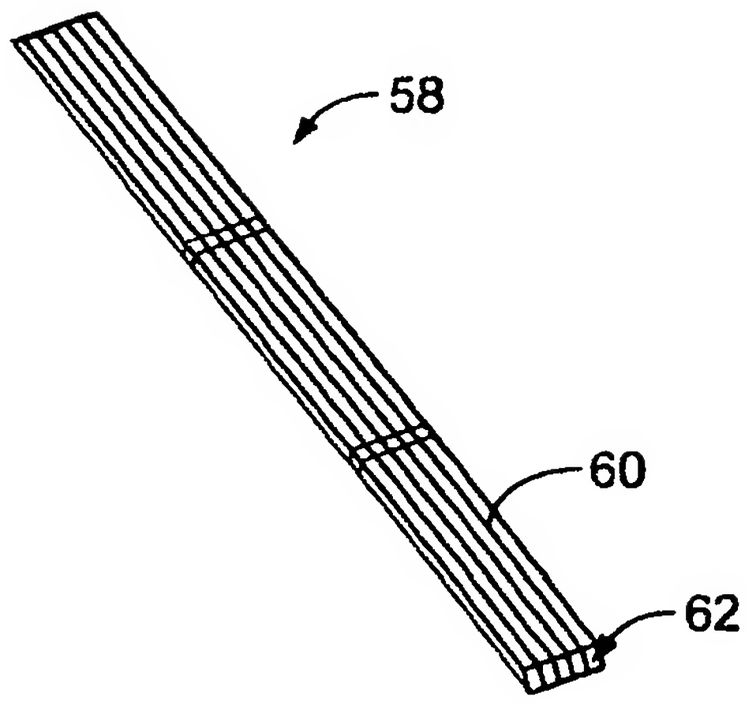

FIG. 11

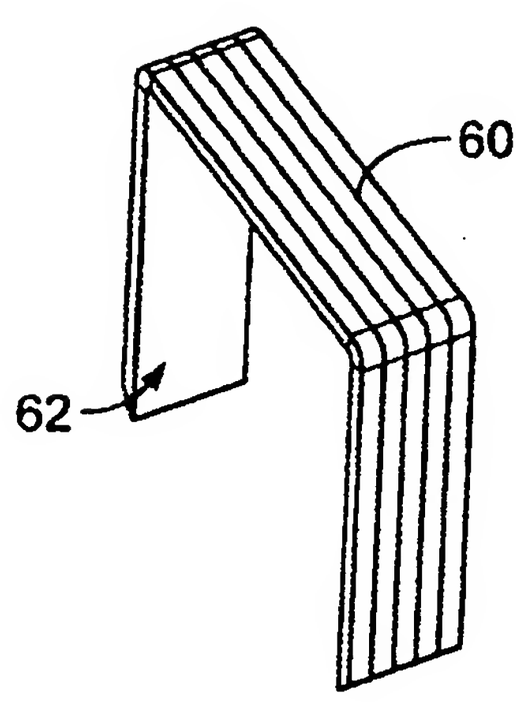

FIG. 12

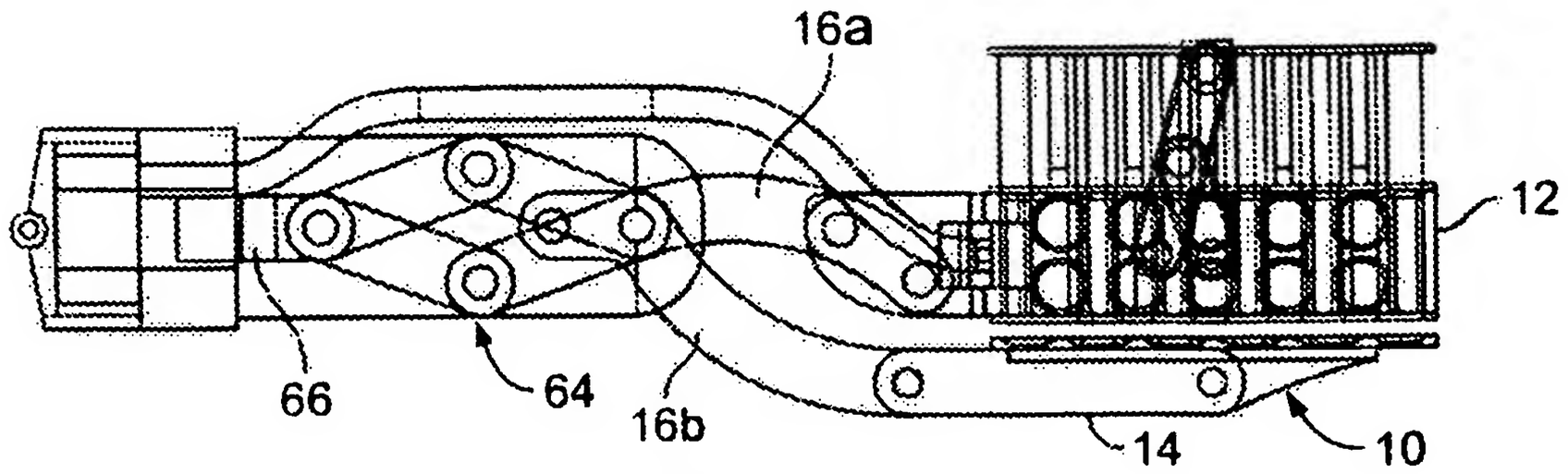

FIG. 13

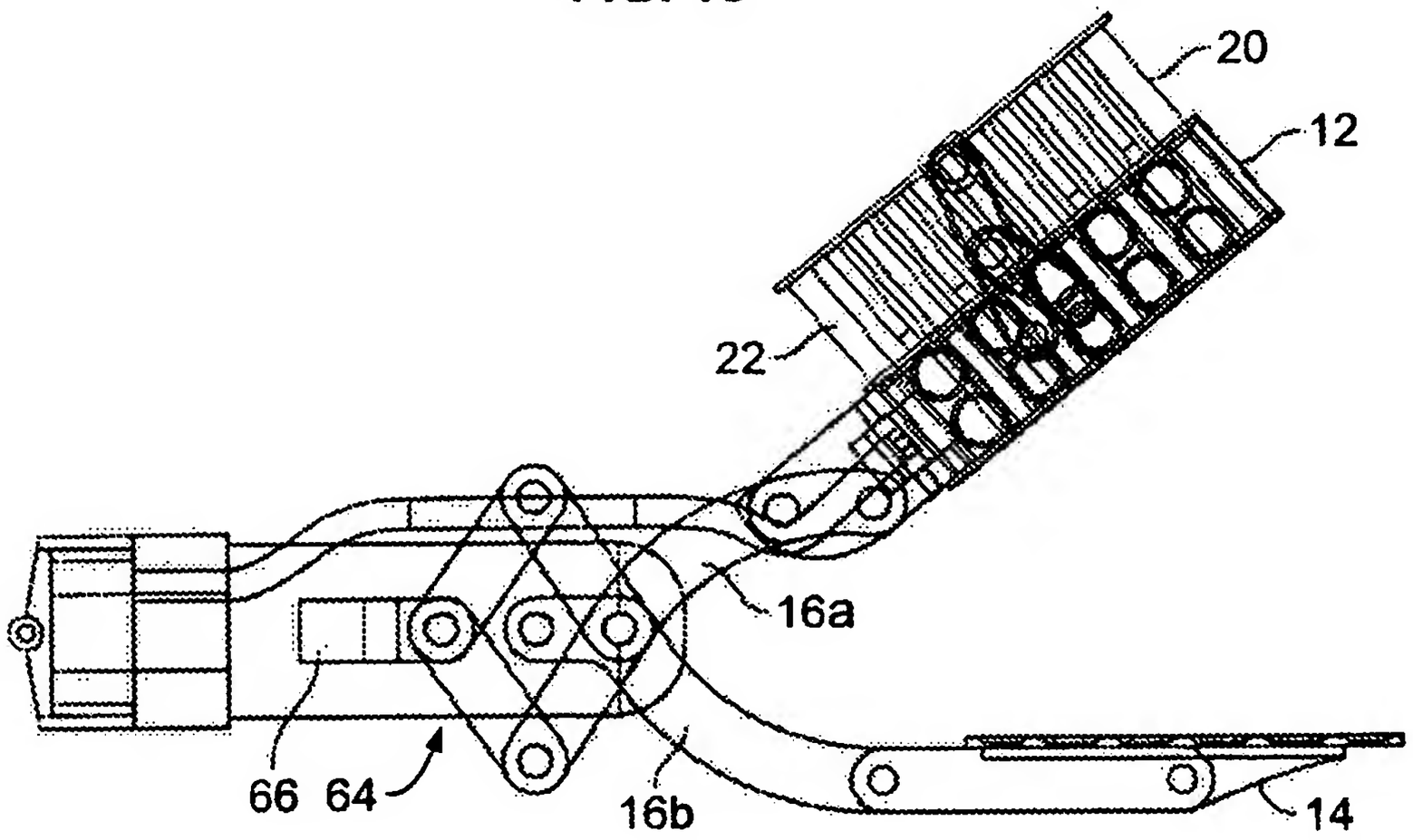

FIG. 14

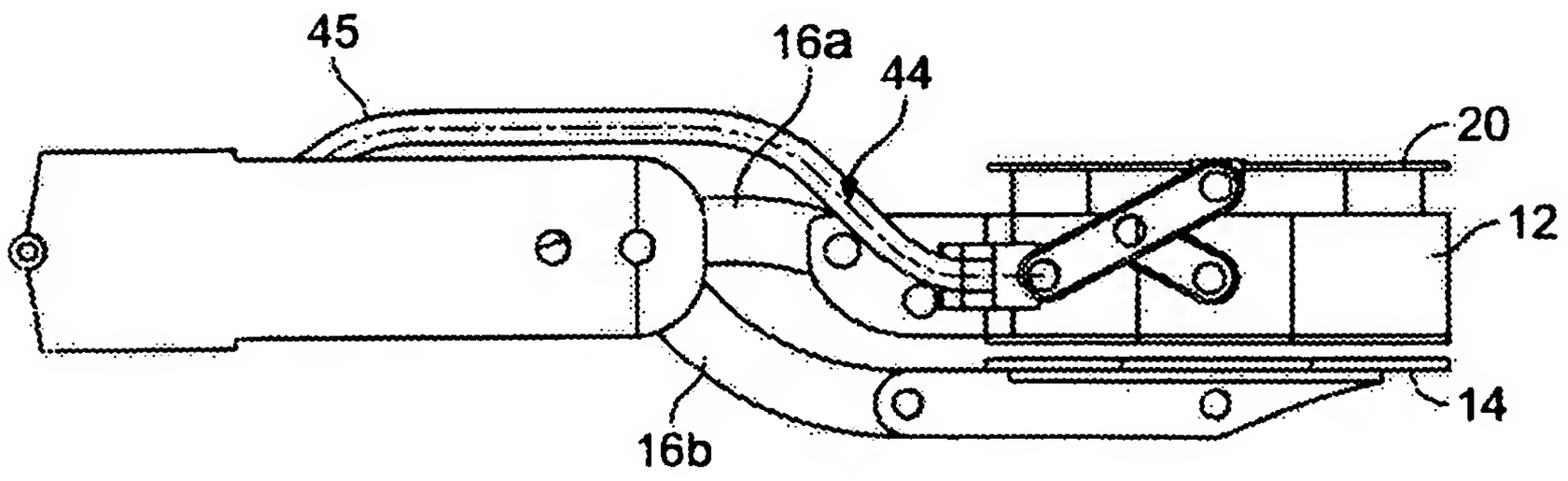

FIG. 15

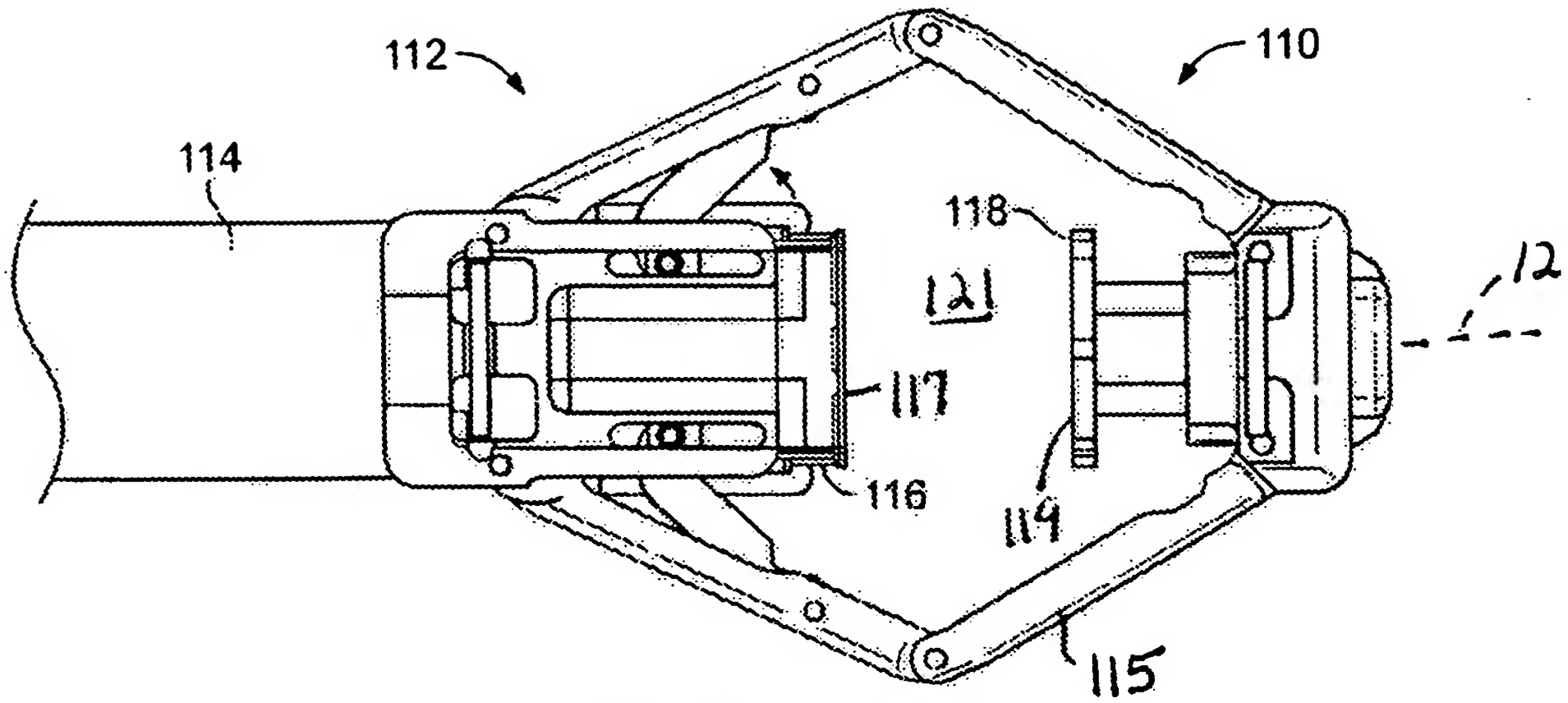
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FIG. 16

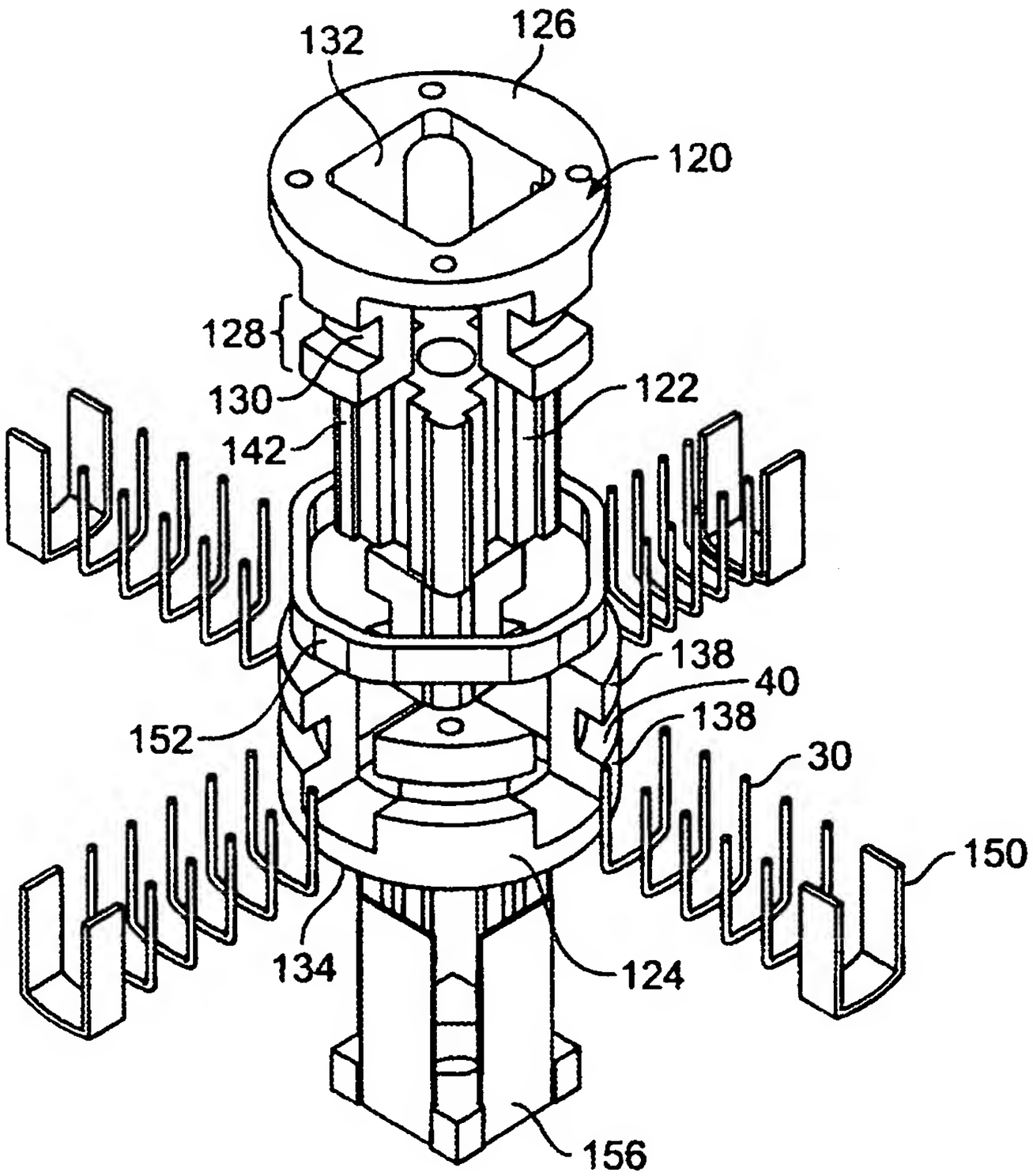
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FIG. 17

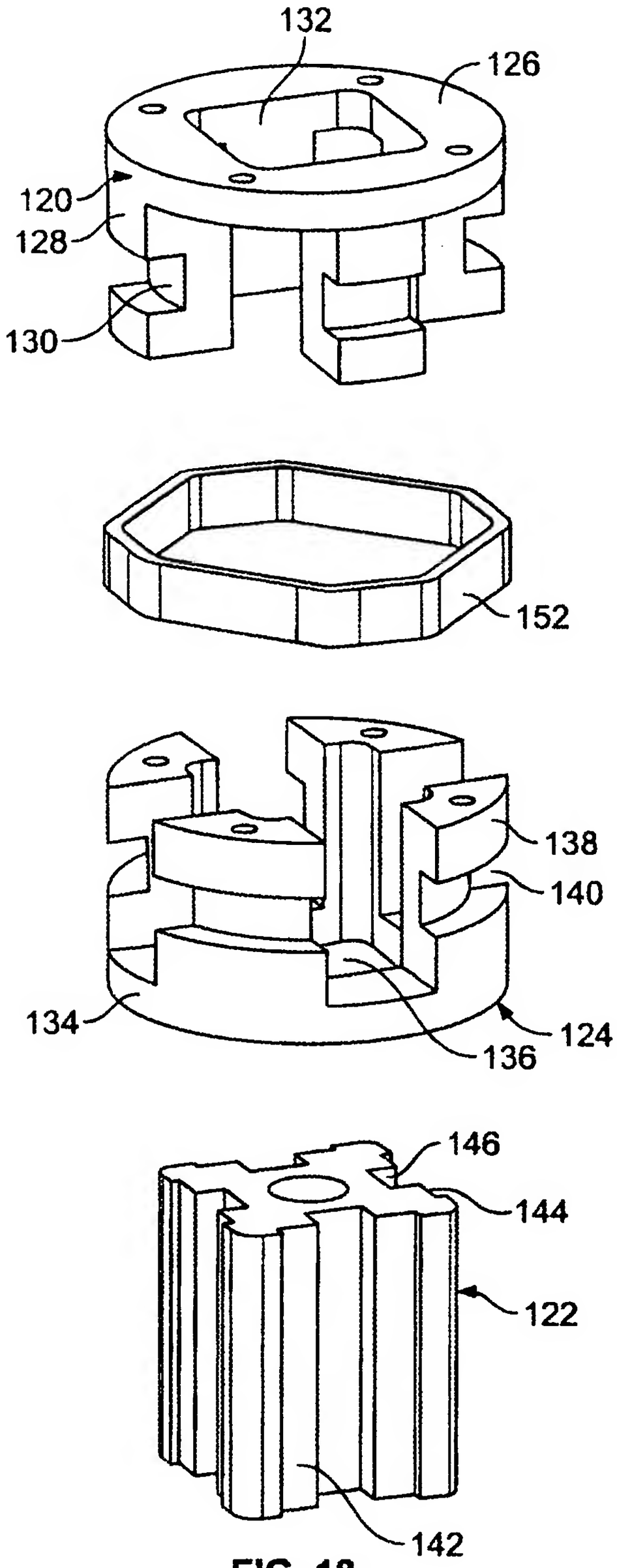
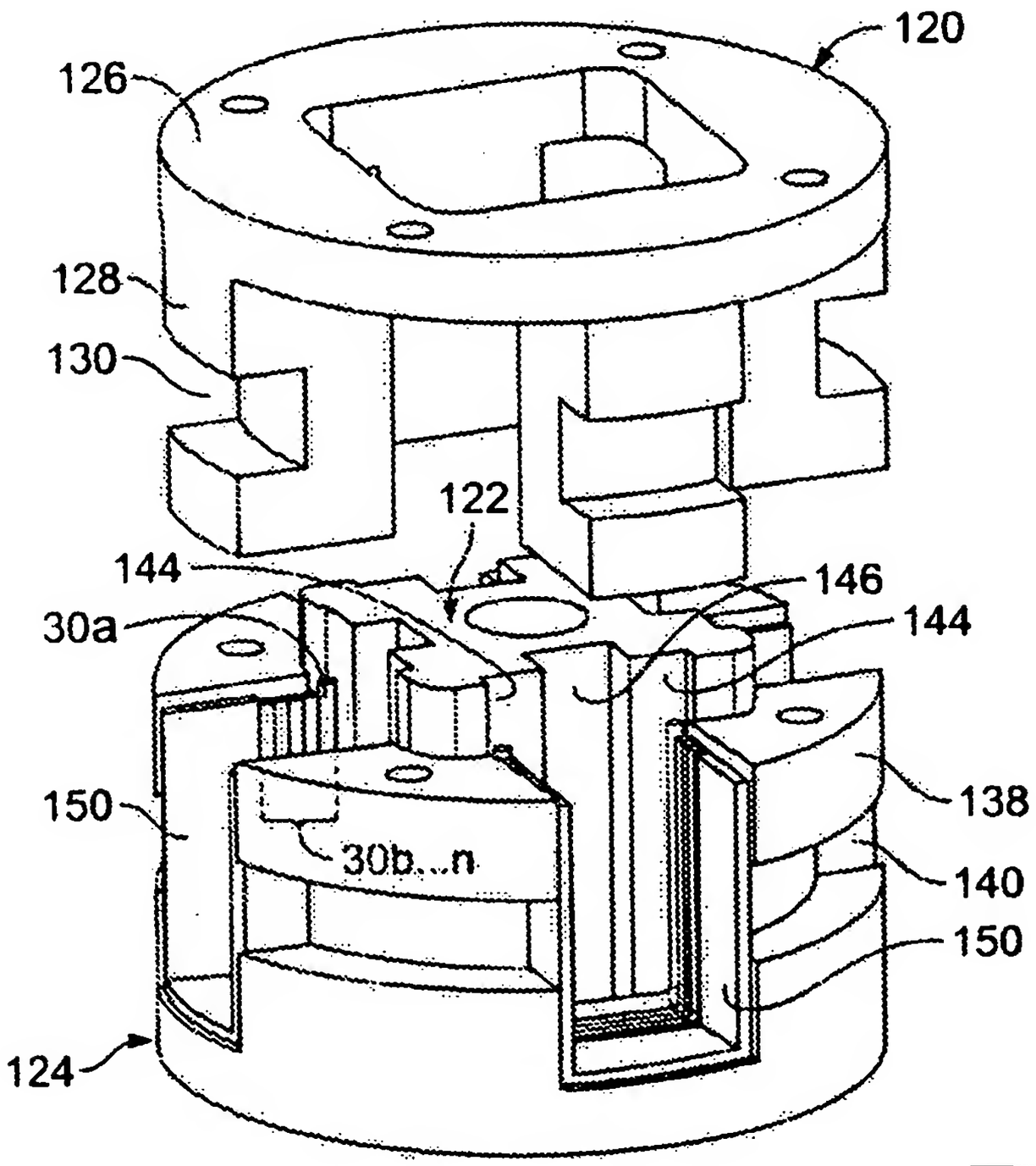


FIG. 18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30b...n
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FIG. 19

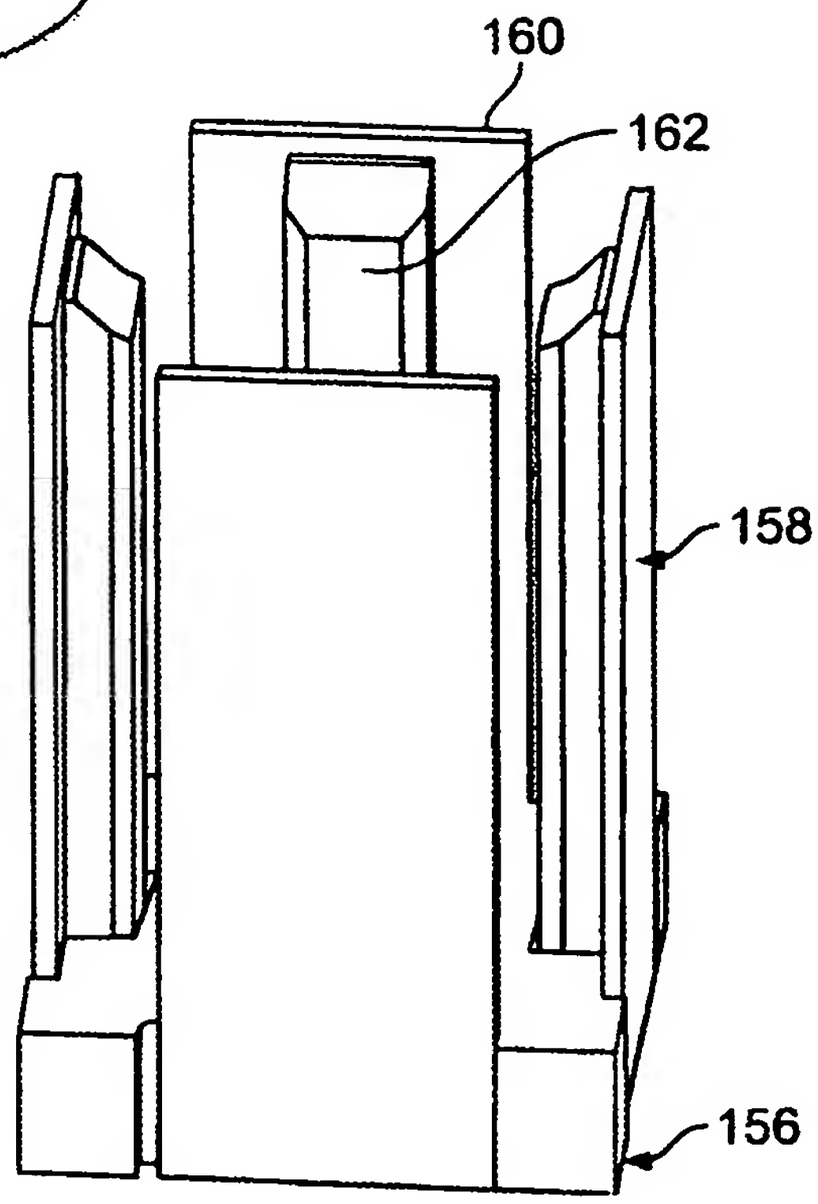
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FIG. 20

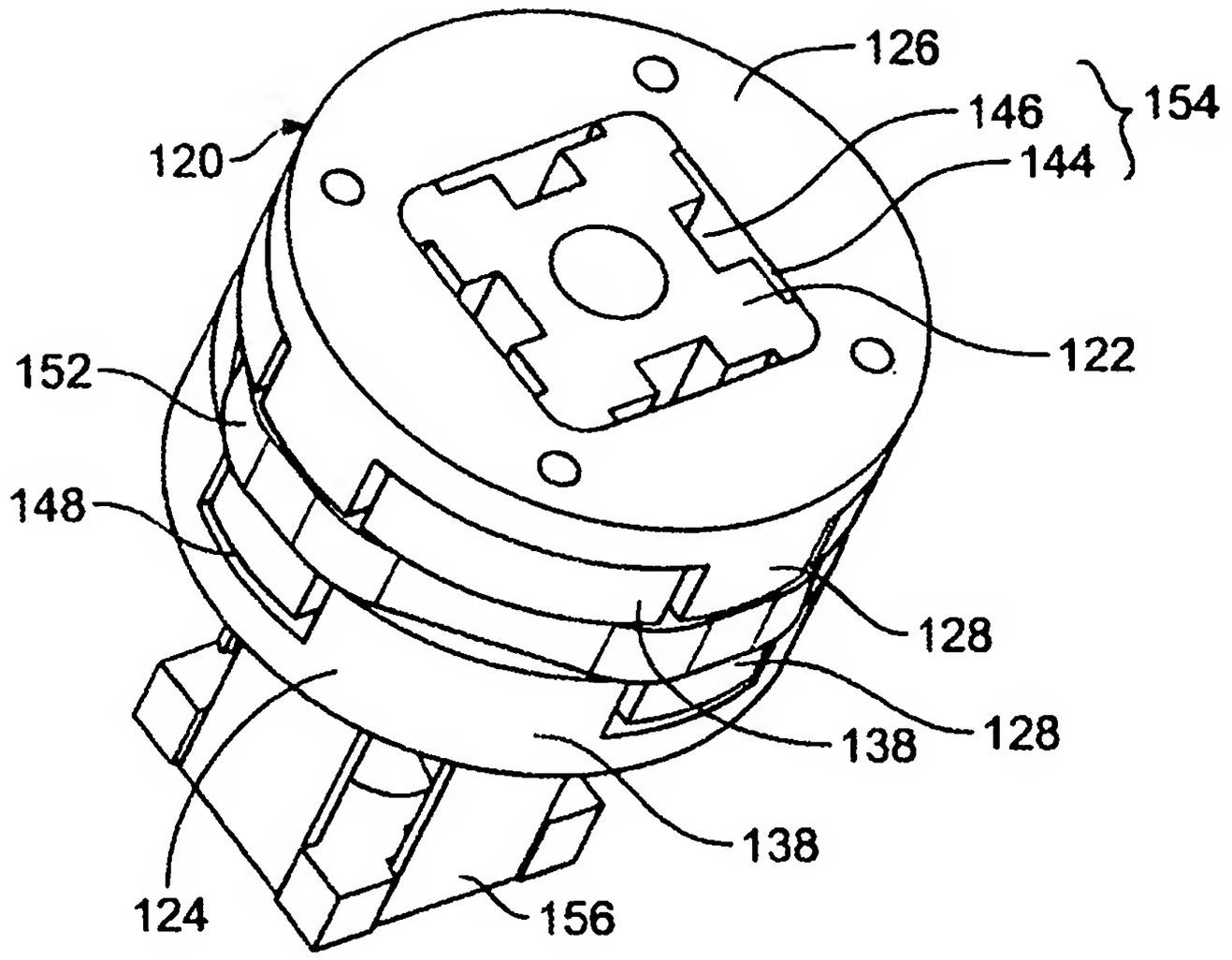

FIG. 21A

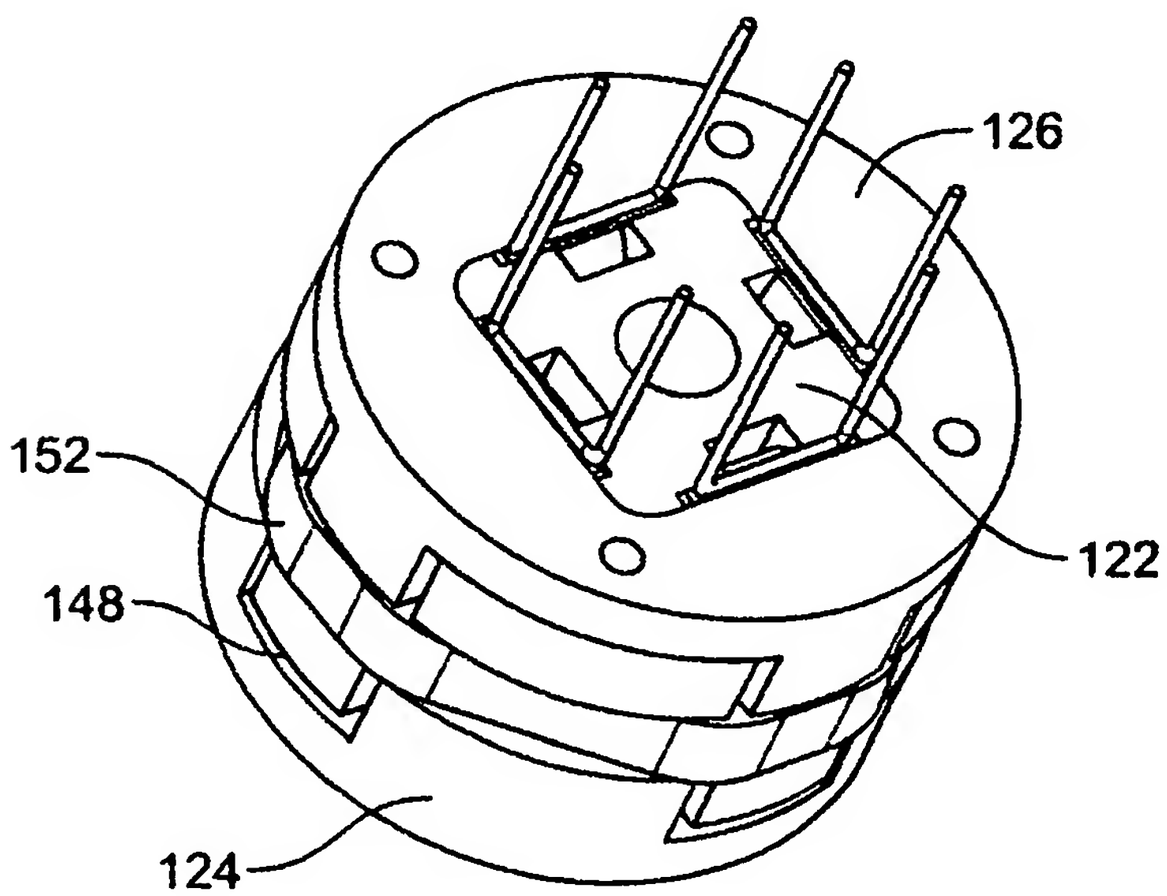

FIG. 21B

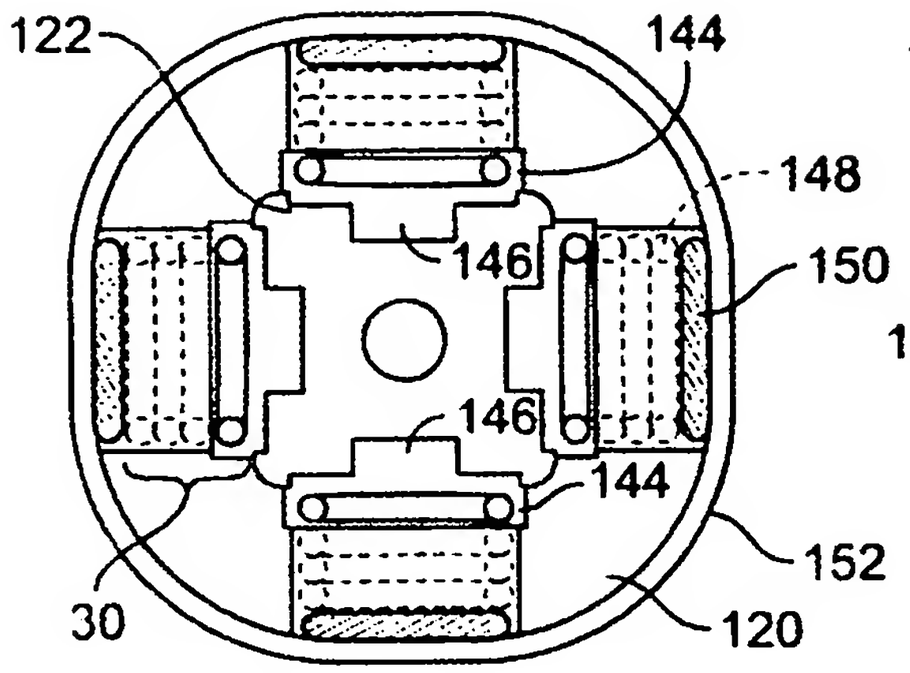

FIG. 22

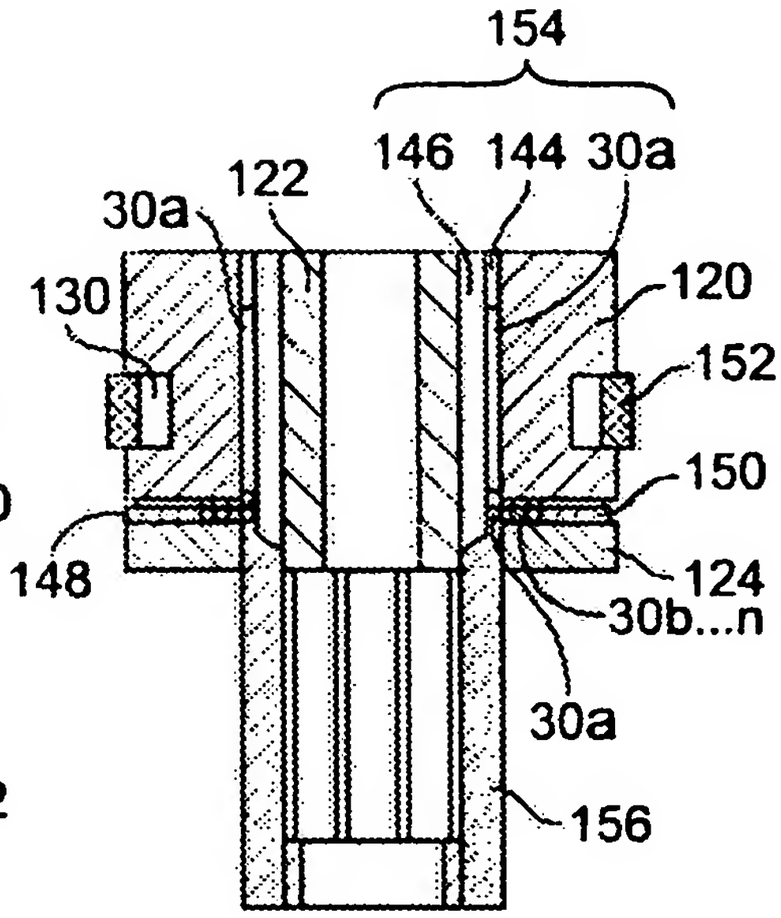

FIG. 23A

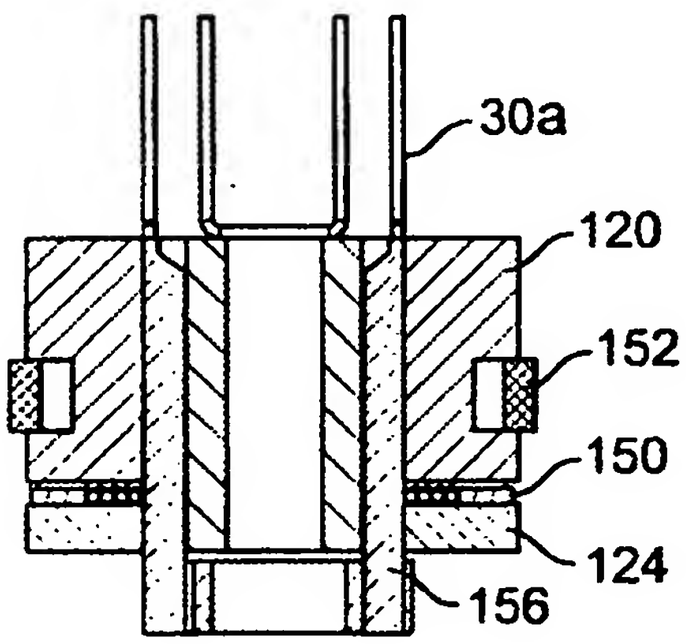

FIG. 23B

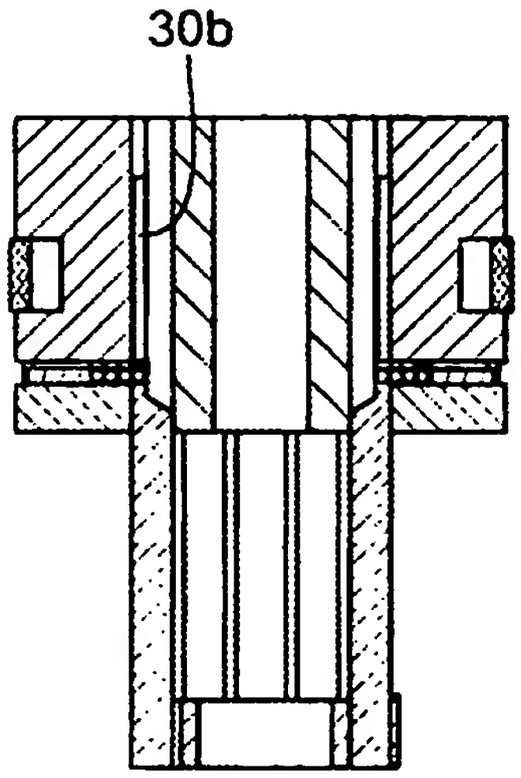

FIG. 23C

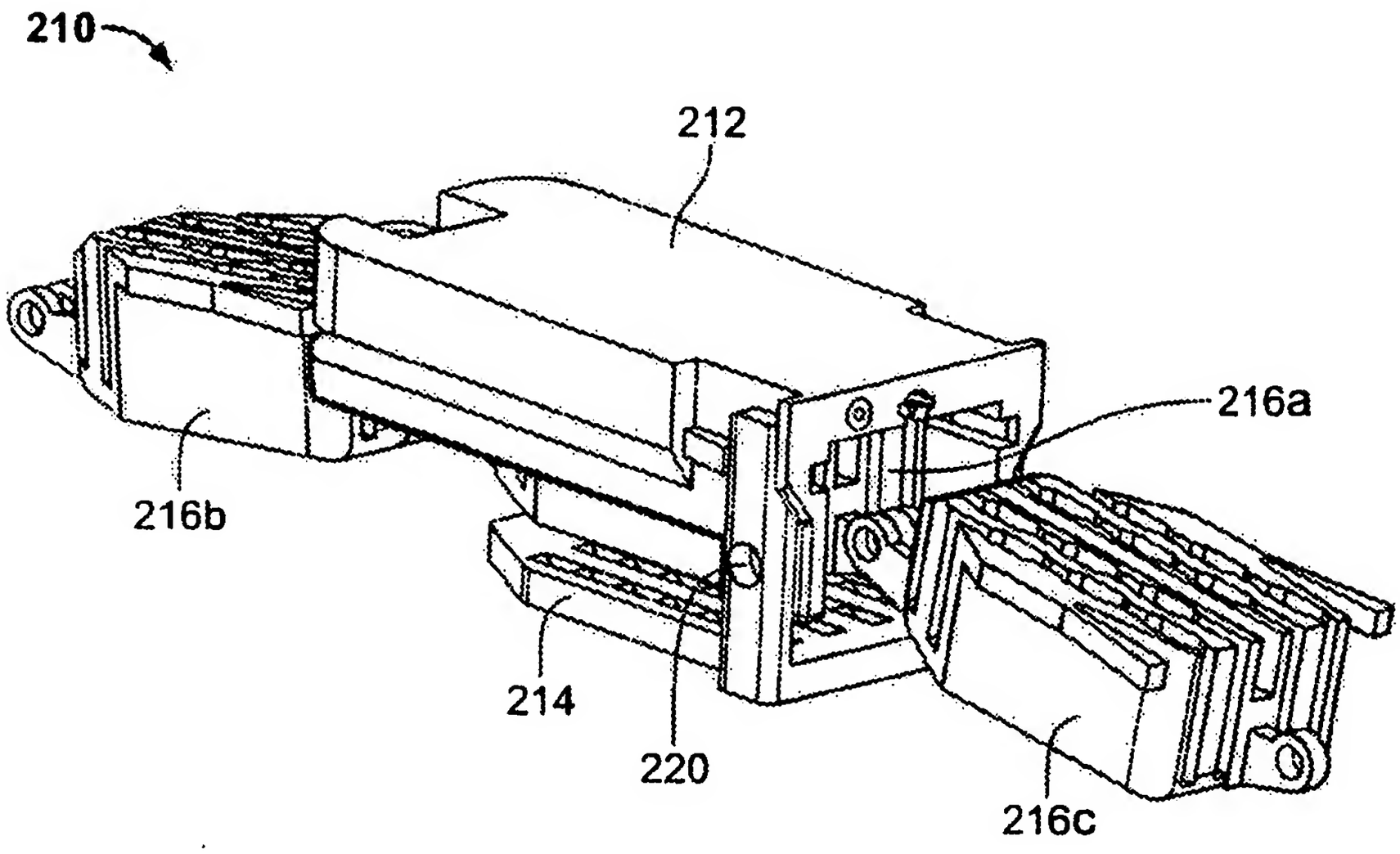

FIG. 24

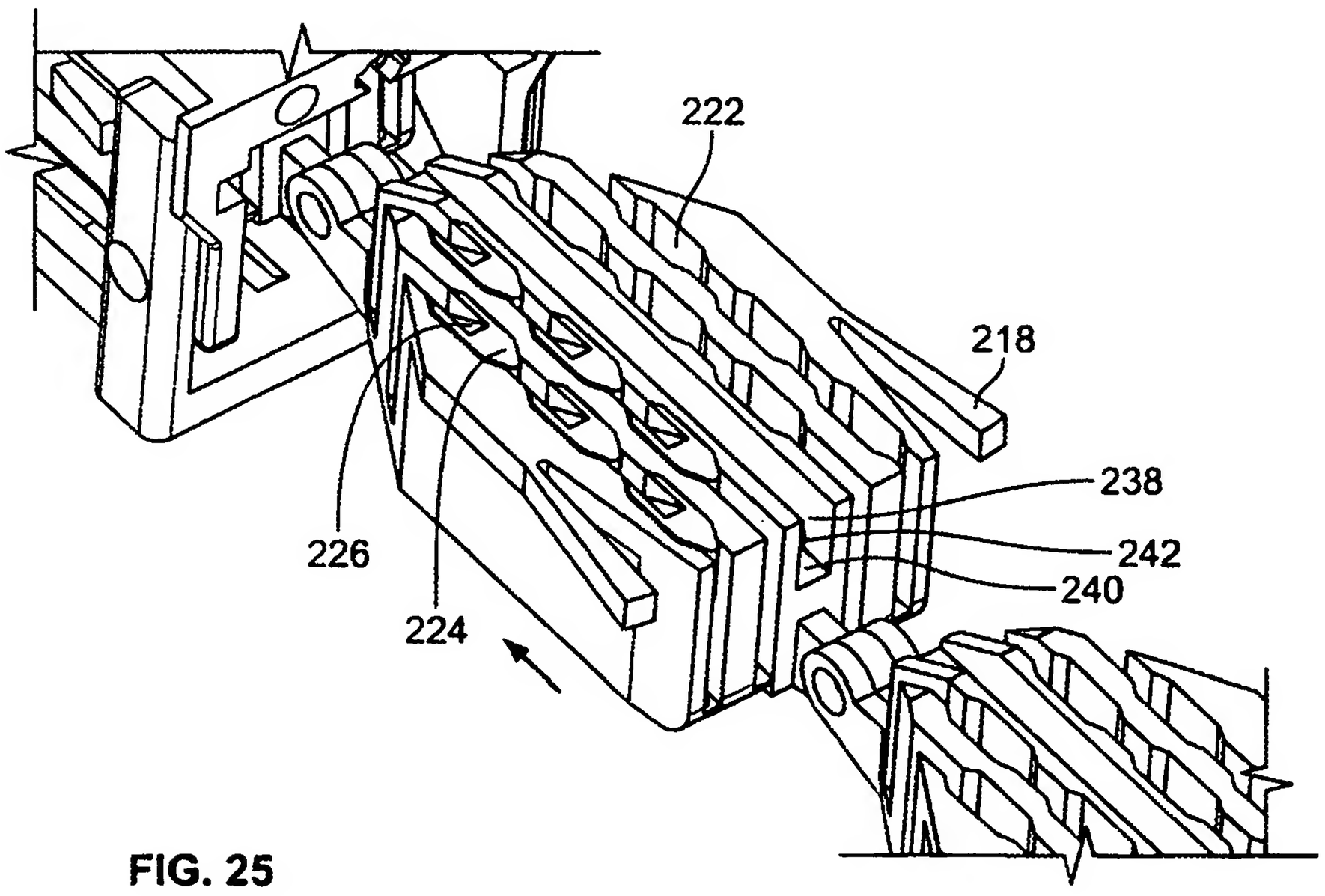

FIG. 25

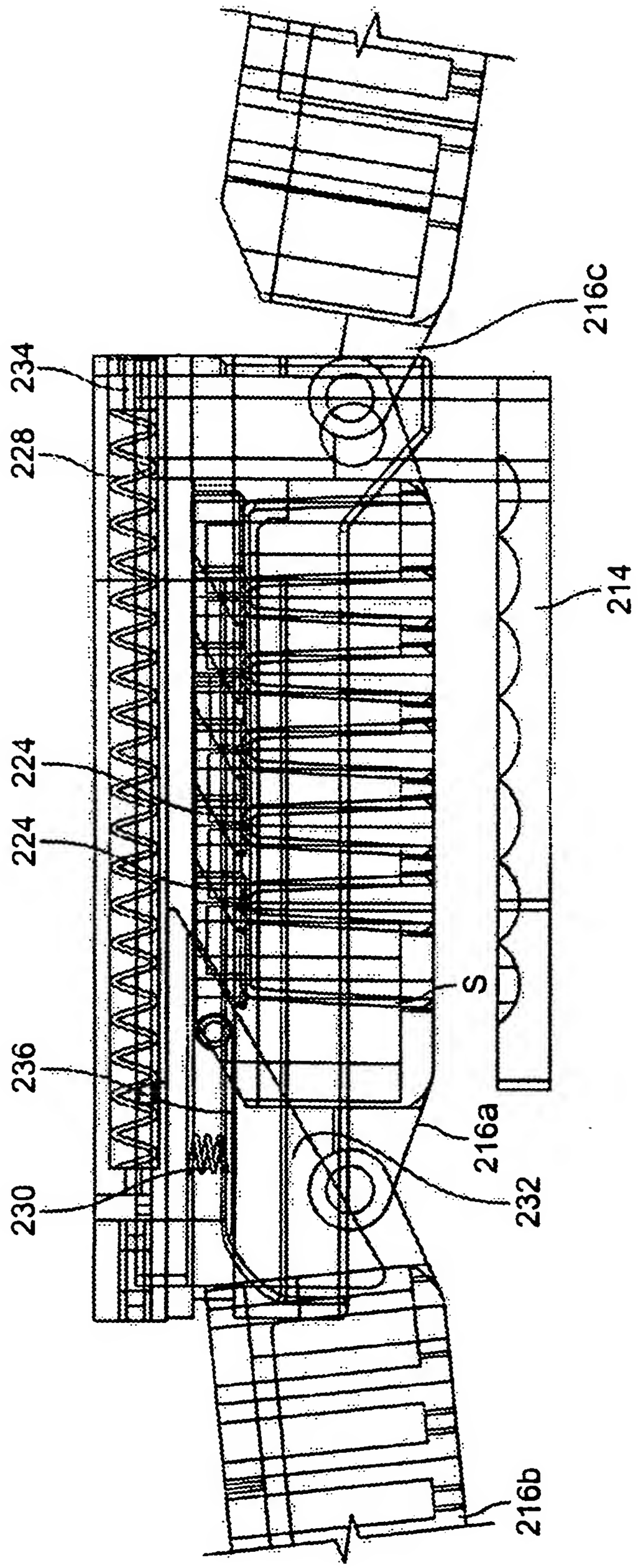

FIG. 26A

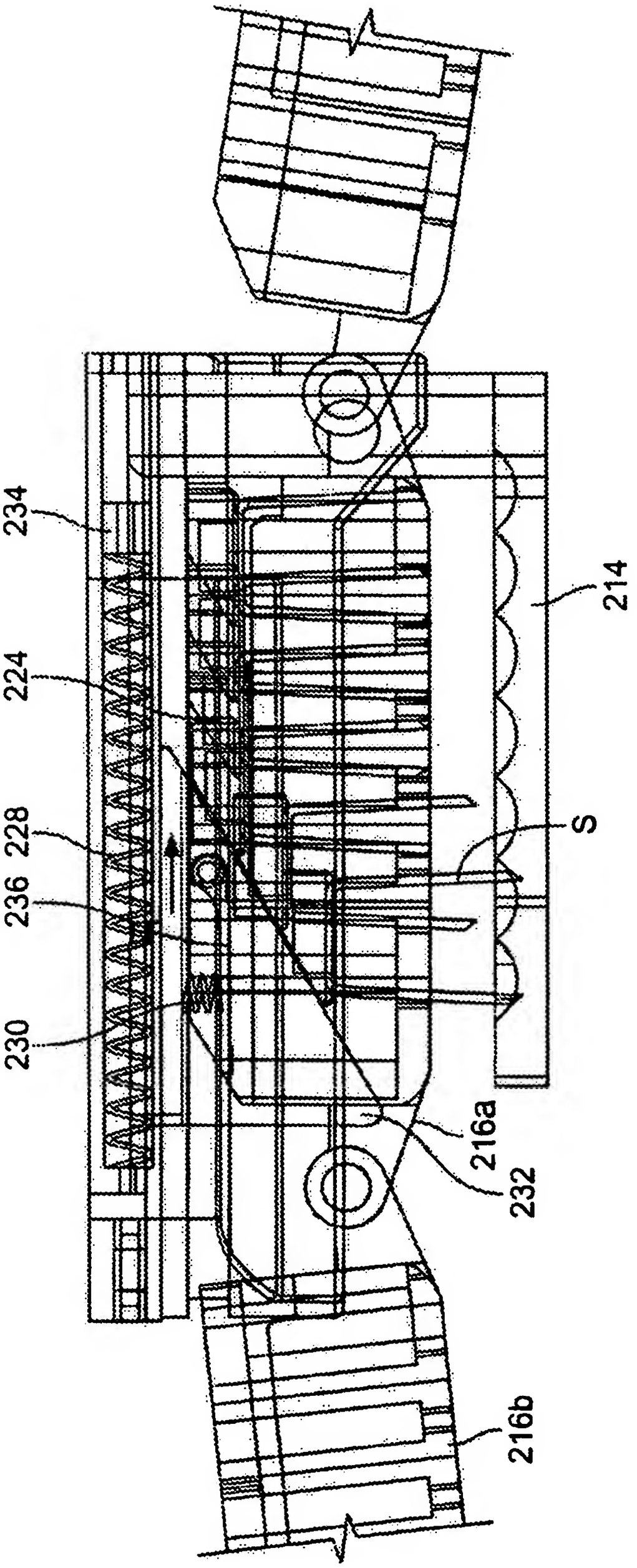

FIG. 26B

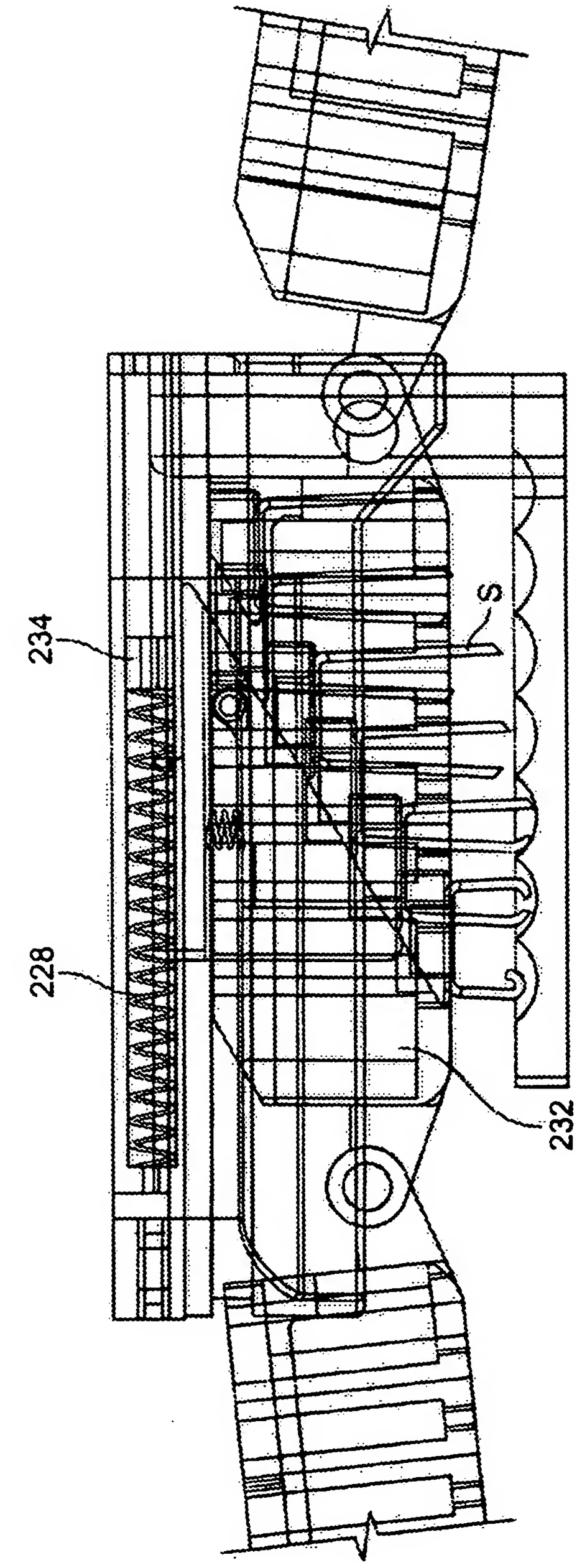

FIG. 26C

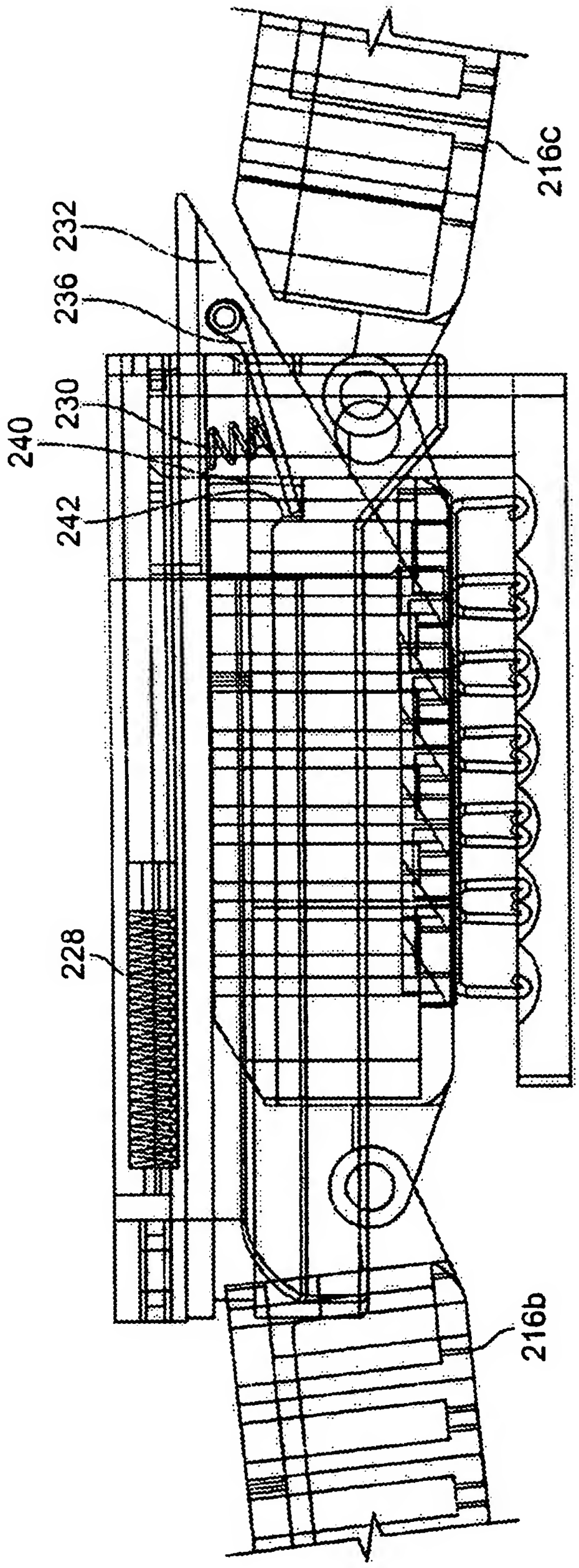

FIG. 26D

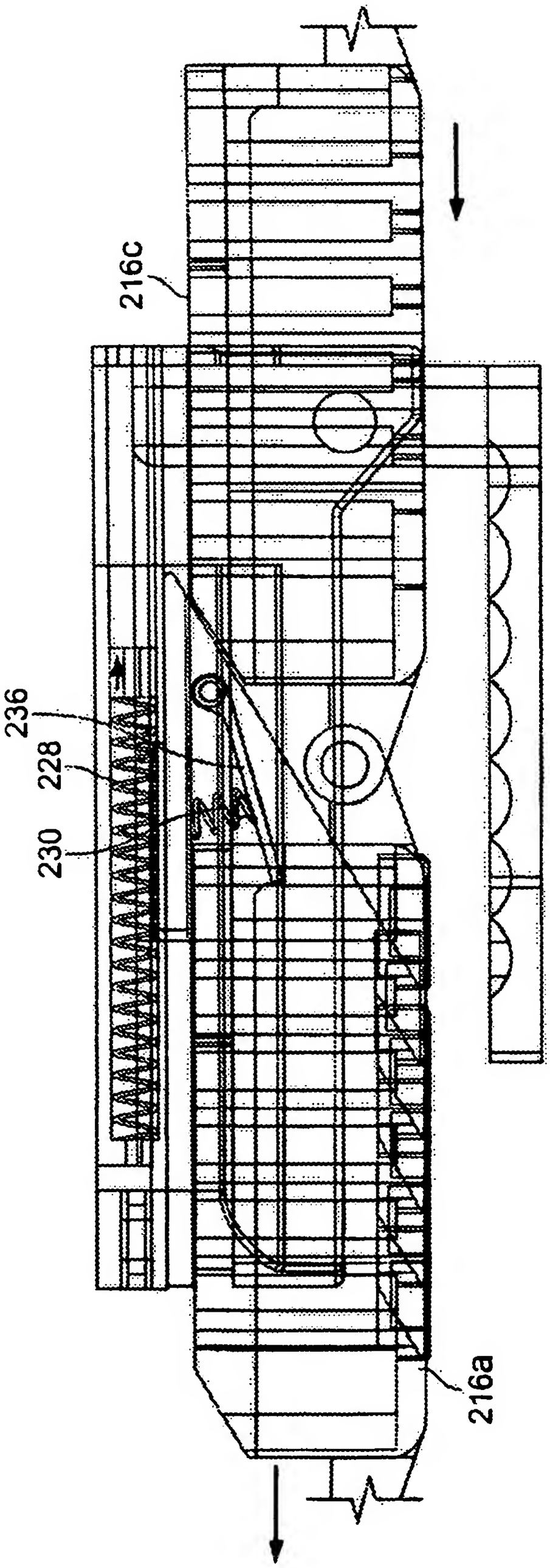

FIG. 26E

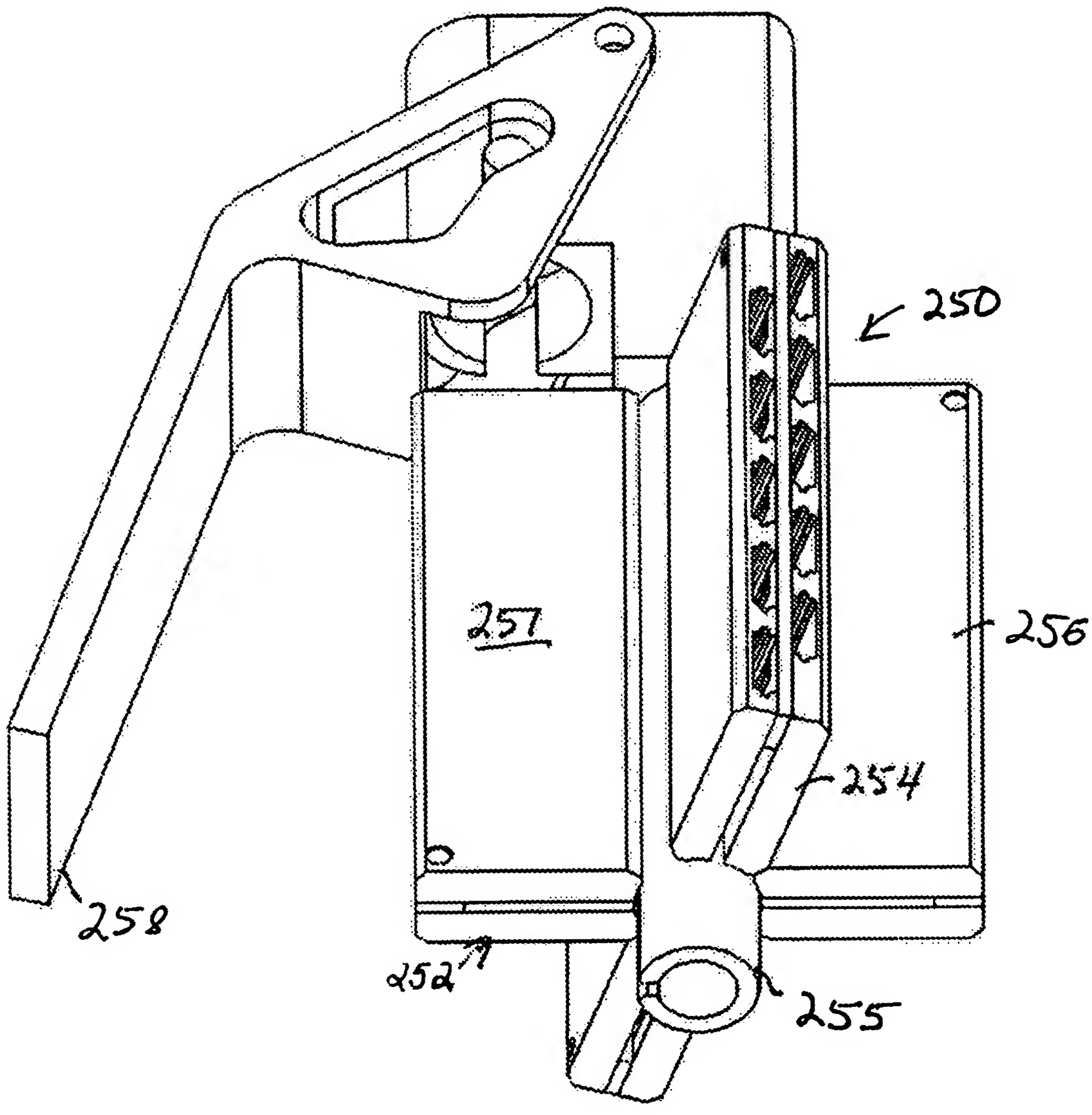

Fig 27

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/063930

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/04 (2010.01)
USPC - 227/175.1
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 17/04, 17/10 (2010.01)
USPC - 227/175.1, 179.1, 180.1; 606/219

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/0190989 A1 (CREWS et al) 14 August 2008 (14.08.2008) entire document	1-15
Y		16-20
Y	US 5,897,562 A (BOLANOS et al) 27 April 1999 (27.04.1999) entire document	16, 18-20
Y	US 5,855,311 A (HAMBLIN et al) 05 January 1999 (05.01.1999) entire document	17
Y	US 7,147,140 B2 (WUKUSICK et al) 12 December 2006 (12.12.2006) entire document	18-20
Y	US 2008/0116244 A1 (RETHY et al) 22 May 2008 (22.05.2008) entire document	19

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
04 January 2010	12 JAN 2010
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)